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1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

3 - - -

4 SURGIQUEST, INC., ) Civil Action

)

5 Plaintiff, )

Counterdefendant, )

6 v. )

)

7 LEXION MEDICAL, LLC, )

)

8 Defendant, )

Counterplaintiff. ) No. 14-382-GMS

9 - - -

10 Wilmington, Delaware  
11 Monday, April 10, 2017  
12 Day 6 of Jury Trial  
8:40 a.m.

13 - - -

14 BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.,  
and a Jury

15  
16 APPEARANCES:

17 DENISE S. KRAFT, ESQ.

DLA Piper LLP

18 -and-

19 FRANCIS W. RYAN, ESQ., and

ERICA PASCAL, ESQ.

DLA Piper LLP

20 (New York, NY)

-and-

21 MELISSA REINCKENS, ESQ.

DLA Piper LLP

22 (San Diego, CA)

23 Counsel for Plaintiff

24

25

1       **APPEARANCES CONTINUED:**

2               DAVID E. MOORE, ESQ., and  
3               BINDU PALAPURA, ESQ.

4               Potter Anderson & Corroon LLP  
5               -and-

6               DAVID G. WILLE, ESQ.,  
7               MEGAN LaDRIERE, ESQ., and  
8               PAUL J. REILLY, ESQ.  
9               Baker Botts LLP  
10              (Dallas, TX)

11                               Counsel for Defendant

12                               - - -

:51:01 1 THE COURT: Good morning. Please, take your  
:51:03 2 seats.

:51:03 3 (Counsel respond "Good morning.")

:51:04 4 THE COURT: Counsel, I wanted to do two things  
:51:11 5 before the jury comes out: find out where you are in terms  
:51:15 6 of progress with these final instructions. The contents,  
:51:20 7 table of contents is a little deceiving insofar as it seems  
:51:24 8 to identify six issues. We have identified 36 separate  
:51:29 9 issues in the footnotes, many of which are not  
:51:36 10 uncomplicated.

:51:39 11 Have you been able to make any additional  
:51:40 12 progress in paring down the disputes? If not, that's fine.  
:51:46 13 I need to know.

:51:47 14 MR. RYAN: Your Honor, we had a meet-and-confer  
:51:49 15 last night. We did make some additional progress. We are  
:51:54 16 going to speak again this morning as to how to narrow down a  
:51:57 17 couple of issues. There will be certain issues I think that  
:52:01 18 will remain open. I think we will be able to report after  
:52:05 19 the lunch break where we stand.

:52:07 20 THE COURT: I would like a more realistic report  
:52:10 21 than this depicts, because there are many, many disputes  
:52:14 22 that remain extant between the parties.

:52:17 23 That is fine. Where are we in terms of the  
:52:19 24 case?

:52:20 25 MR. RYAN: We are going to present a few

1 witnesses today, plus some deposition testimony, Your Honor.  
2 We understand that plaintiff intends to -- Lexion intends to  
3 have a rebuttal case, with I think three or four witnesses  
4 that will last approximately, I think, if we timed it, two  
5 additional hours.

6 That will bring us tomorrow to a dangerous  
7 point, we think, regarding how much we can get done  
8 including closing tomorrow.

9 THE COURT: You have until tomorrow to complete  
10 this case, counsel. You are going to need to think about  
11 perhaps paring down your proofs. I am not going to try this  
12 case beyond Tuesday.

13 MR. WILLE: Your Honor, the feedback that would  
14 be helpful from the Court is when you would expect to begin  
15 closing arguments and jury instructions.

16 THE COURT: I would have preferred to begin to  
17 instruct the jury in the morning and then have closings.  
18 That would be my goal. I would prefer not to have to be in  
19 a conference with you folks discussing final jury  
20 instructions tomorrow. I would rather, if we could, get  
21 that done today.

22 That's why your realistic report by the lunch  
23 hour as to what disputes remain is important.

24 Frankly, counsel, I and my law clerk have found  
25 through the course of these proceedings representations have

1       been made as to what the law is. We have found those  
2       representations not to be altogether accurate, on both  
3       sides. It doesn't require a response. It is an  
4       observation. A little harsh, but it is a fact, one that has  
5       been quite frustrating to me.

6               I won't comment beyond that.

7               That's my goal, Mr. Wille. Your reaction.

8               MR. WILLE: Your Honor, I am not sure, given the  
9       number of witnesses that are remaining, that it's possible  
10      to get done today.

11              THE COURT: Then you are going to have to think  
12      about cutting down your witnesses.

13              MR. WILLE: Okay.

14              THE COURT: You, Mr. Ryan?

15              MR. RYAN: Your Honor, we have Mr. Tegan to  
16      finish, we have Mr. Collins to testify today, Ms. Carol  
17      Scott will testify today. We have deposition read-ins, and  
18      Keith Ugone, our damages expert. All that will be done  
19      today.

20              THE COURT: Maybe it will. Maybe it won't. You  
21      are going to need to think about cutting your down your  
22      case.

23              MR. RYAN: We have already, Your Honor.

24              THE COURT: Maybe you need to cut it down more.

25              MR. RYAN: Understood.

:55:03 1 THE COURT: How many minutes or hours of  
:55:07 2 deposition testimony?

:55:08 3 MR. RYAN: About 20 minutes.

:55:11 4 MS. PASCAL: It's 40 minutes split between the  
:55:13 5 parties, I believe we have --

:55:15 6 THE COURT: Is this testimony that the parties  
:55:16 7 have determined is critical to your proofs?

:55:20 8 MR. RYAN: Our 20 minutes, we have 20 minutes  
:55:22 9 designated of their sales reps testifying that the decision  
:55:26 10 to purchase AirSeal --

:55:27 11 THE COURT: There has been a lot of evidence in  
:55:30 12 this case, both expert and fact, that has been cumulative.  
:55:33 13 I have a standing rule against cumulative expert testimony.  
:55:36 14 It has not been adhered to. Neither side has objected when  
:55:41 15 that occurred. I noticed it. I unfortunately have had to  
:55:45 16 inject myself into this case more than I usually do or like  
:55:48 17 to do. There has been time wasted.

:55:51 18 Mr. Ryan, you don't need you to signify when I  
:55:55 19 say something.

:55:55 20 How many hours do you think it's going to take  
:56:02 21 you to finish your case?

:56:24 22 MR. RYAN: Your Honor, about two and a quarter  
:56:26 23 hours of testimony total and maybe 20 minutes of deposition  
:56:31 24 testimony total.

:56:32 25 THE COURT: You, Mr. Wille? How many hours of

:56:37 1 evidence do you intend to use?

:56:46 2 You can take a moment and confer with your  
:56:48 3 colleague.

:56:48 4 MR. WILLE: Just a second.

:57:00 5 Between -- the cross, somewhere around two  
:57:04 6 hours, and about an hour to an hour and a half on rebuttal.

:57:11 7 THE COURT: Two hours on your direct?

:57:17 8 MR. WILLE: Actually, on cross. Cross of their  
:57:20 9 witnesses that are remaining.

:57:21 10 THE COURT: So you are estimating two and a  
:57:24 11 half, you said?

:57:27 12 MS. PASCAL: With the deposition, yes.

:57:29 13 THE COURT: How much cross do you anticipate?

:57:32 14 MR. WILLE: Remember, I still have a witness to  
:57:34 15 cross that is not included in their total.

:57:37 16 About two hours, Your Honor. Two hours of cross  
:57:42 17 between all those witnesses.

:57:46 18 I would add, Mr. Tegan we were going the call in  
:57:49 19 our case-in-chief. So this cross will be a little longer  
:57:52 20 than the others.

:57:56 21 THE COURT: You will need to reassess at lunch.  
:58:00 22 Let's see where we are going. Okay.

:24:49 23 (The jury entered the courtroom.)

:02:17 24 THE COURT: Good morning, members of the jury.  
:02:20 25 Did you have a good weekend? Why don't you take your seats

Tegan - cross

1 and we'll resume with Mr. Tegan.

2 ... JEREMY TEGAN, having been previously  
3 duly sworn as a witness, was examined and  
4 testified further as follows ...

5 THE COURT: Good morning, Mr. Tegan. You remain  
6 under oath.

7 THE WITNESS: Yes, sir.

8 THE COURT: Mr. Wille, your witness.

9 CROSS-EXAMINATION

10 BY MR. WILLE:

11 Q. Good morning, Mr. Tegan.

12 A. Good morning.

13 Q. Now, Mr. Tegan, you indicated on Friday that you  
14 received about \$600,000 for the sale of your stock when  
15 SurgiQuest was sold to ConMed; is that correct?

16 A. That's correct.

17 Q. And it was the plan all along for SurgiQuest, was to  
18 get acquired by a larger company; is that correct?

19 A. No, that's not true.

20 MR. WILLE: May have Exhibit 263, please.

21 BY MR. WILLE:

22 Q. Sir, Exhibit 236 is a strategic plan for 2013 to 2017;  
23 is that correct?

24 A. That's correct.

25 Q. All right. And let's go to Page 21 of the exhibit,



Tegan - cross

:03:29 1 please. So you would agree that this shows some bullet  
:03:36 2 points of strategies for 2014; is that correct?

:03:39 3 A. That's correct.

:03:41 4 Q. All right. And go to the next slide, please. It also  
:03:44 5 shows some bullet points for 2015; is that correct?

:03:47 6 A. Yes, sir.

:03:48 7 Q. Okay. Now let's go to the plan for 2016. The beach;  
:03:53 8 right?

:03:53 9 A. That's correct.

:03:54 10 Q. Be on a beach. Sell the company by the end of 2015.  
:03:59 11 That was your goal; right?

:04:00 12 A. That wasn't the only goal of the company, sir.

:04:02 13 Q. But the goal was accomplished; right? The company was  
:04:05 14 sold by the end of 2015?

:04:06 15 A. During the 2016 year, we were also working  
:04:10 16 aggressively on an IPO. We were going to take the company  
:04:14 17 public in either late 2015 or early 2015 -- or, excuse me,  
:04:18 18 late 2015 or early 2016.

:04:20 19 Q. Okay. But the goal was to be on the beach by 2016; is  
:04:24 20 that correct?

:04:24 21 A. I think that was a whimsical slide.

:04:28 22 Q. Okay. Thank you.

:04:30 23 Now, on Friday you talked about some of the  
:04:31 24 methods that SurgiQuest uses to promote the AirSeal System;  
:04:35 25 is that correct?

Tegan - cross

:04:35 1 A. Yes, sir.

:04:36 2 Q. And one of those is simply promotion by sales reps in  
:04:39 3 one-on-one meetings with surgeons; right?

:04:42 4 A. Yes.

:04:43 5 Q. Okay. And one of the things that SurgiQuest does to  
:04:47 6 promote sales of the products is hand out folders of  
:04:50 7 materials at trade shows; is that correct?

:04:52 8 A. Yes.

:04:52 9 MR. WILLE: Permission to approach the witness,  
:04:54 10 Your Honor.

:04:54 11 THE COURT: Yes, sir.

:05:00 12 (Mr. Wille handed an exhibit to the witness.)

:05:09 13 BY MR. WILLE:

:05:09 14 Q. Mr. Tegan, I've handed you Exhibit, Lexion Exhibit 870  
:05:14 15 and Lexion Exhibit 871. With the Court's permission, to the  
:05:20 16 extent, in the interests of time, may I ask him about kind  
:05:24 17 of both of these in one question?

:05:26 18 THE COURT: Sure.

:05:27 19 BY MR. WILLE:

:05:27 20 Q. Okay. Mr. Tegan, both Exhibit 870 and 871 are folders  
:05:31 21 of materials that were handed out by SurgiQuest at trade  
:05:34 22 shows; is that correct?

:05:35 23 A. Sparingly, yes. We typically would provide  
:05:38 24 information on small flash drives or jump drives that  
:05:41 25 perhaps contain less information, but generally speaking,

Tegan - cross

:05:44 1 these were sometimes available, yes about.

:05:45 2 Q. Okay. Were those also provided to sales reps so that  
:05:48 3 they could leave them behind with customers?

:05:50 4 A. Complete packets were typically not. We usually left  
:05:53 5 it at the sales reps to order the items that they wanted to  
:05:57 6 have to leave for the physicians. Some would leave a lot of  
:06:01 7 information. Some would leave just a little. It really  
:06:04 8 kind of depended on the sales representatives.

:06:05 9 Q. Now, the term AirSeal is all over these materials.  
:06:08 10 You would agree?

:06:10 11 A. Yes.

:06:10 12 Q. And that trademark, it's also on your machine, is that  
:06:13 13 correct, that you sell?

:06:14 14 A. Yes, sir.

:06:14 15 Q. Okay. So AirSeal is used all over your promotional  
:06:18 16 materials; is that correct?

:06:18 17 A. It is.

:06:19 18 Q. All right. And in each of those folders is the cost  
:06:22 19 comparison sheet that the jury has seen so many times this  
:06:25 20 week; is that correct?

:06:26 21 A. Yes.

:06:26 22 Q. All right. As well as the statement of safety and  
:06:29 23 effectiveness; is that correct?

:06:30 24 A. Yes.

:06:31 25 Q. Let me ask Mr. Barnes to put up Exhibit Lexion

Tegan - cross

:06:39 1 Exhibit 212, please.

:06:43 2 Now, another way SurgiQuest promotes the sale of  
:06:45 3 a product is for its sales reps to send e-mails to customers  
:06:49 4 attaching materials; is that correct?

:06:50 5 A. Yes, sir.

:06:52 6 Q. All right. So Exhibit 212, if we can zoom into the  
:06:55 7 top, is from Dean Maskel. He's a sales rep for SurgiQuest;  
:07:00 8 is that correct?

:07:00 9 A. He was for a while, yes, sir.

:07:03 10 Q. Okay. And you see a list of attachments to the e-mail  
:07:12 11 listed there?

:07:14 12 A. Yes, sir.

:07:15 13 Q. Okay. And one of the attachments listed is L.  
:07:21 14 Kavoussi Urology.PDF; right?

:07:23 15 A. That's correct.

:07:23 16 Q. You know what that is; right?

:07:25 17 A. Many very familiar with that.

:07:27 18 Q. That is a medical journal article regarding some  
:07:29 19 clinical results achieved; is that correct?

:07:32 20 A. Yes, sir.

:07:33 21 Q. And those clinical results were achieved using the DPS  
:07:38 22 version of the AirSeal; is that correct?

:07:40 23 A. Yes, sir.

:07:40 24 Q. Okay. And this paper here is sometimes also referred  
:07:45 25 to as the, one of the Herati papers; correct? He was one of

Tegan - cross

:07:50 1 the co-authors?

:07:51 2 A. Yes, sir.

:07:51 3 Q. And that paper was on SurgiQuest's website for years;  
:07:54 4 is that correct?

:07:54 5 A. Yes, sir.

:07:54 6 Q. It was on the website for years even after the DPS was  
:07:58 7 taken off the market; is that correct?

:07:59 8 A. Yes, sir.

:08:00 9 Q. Okay. So it is true that SurgiQuest in the  
:08:03 10 marketplace uses clinical data on the DPS to promote the  
:08:10 11 sale of the IFS; is that correct?

:08:12 12 A. At the time we were, yes.

:08:15 13 Q. Okay. And you felt that was fine because the two  
:08:17 14 units operate similarly; is that correct?

:08:21 15 A. There was some differences between the performance and  
:08:25 16 how they work, but generally speaking, it provided stable  
:08:28 17 pneumoperitoneum and continuous smoke evacuation and  
:08:33 18 abdominal reactive of the abdominal cavity.

:08:34 19 Q. Now, the Kavoussi article, you were aware that many  
:08:38 20 sales reps send sent this out. This is this is not some  
:08:43 21 aberrational e-mail?

:08:45 22 A. I don't know that many reps sent it out. It was sent  
:08:47 23 out.

:08:48 24 Q. It was on your website?

:08:50 25 A. Yes.

Tegan - cross

:08:50 1 Q. All right. There's also a document here, AORN

:08:53 2 Physician Statement and JCAHOS smoke exposure. Those deal

:09:02 3 with surgical smoke; correct?

:09:03 4 A. Yes.

:09:03 5 Q. Safety issues having to deal with surgical smoke; is

:09:06 6 that correct?

:09:07 7 A. I believe so, yes.

:09:10 8 Q. And do you see the cost comparison was included here

:09:14 9 well?

:09:15 10 A. Yes.

:09:19 11 Q. Now, the jury has seen the cost comparison. I will

:09:22 12 put it up. And you're familiar with it?

:09:24 13 A. Yes, sir.

:09:25 14 Q. So I will put it up here if you want, but let's see if

:09:28 15 we can do without it.

:09:29 16 So you agree that the cost comparison indicates

:09:31 17 that a CO2 warmer/humidifier is not needed for a

:09:35 18 hysterectomy; is that right?

:09:38 19 A. Yes, I would agree with that.

:09:41 20 Q. Okay. And the cost comparison chart also indicates

:09:44 21 that a CO2 warmer/humidifier is not needed for a

:09:48 22 prostatectomy; is that correct?

:09:50 23 A. When AirSeal is used, that's correct.

:09:52 24 Q. All right. Actually, let's put up Joint Exhibit 1,

:09:55 25 please. And let's zoom in on one of those -- yes, that's

Tegan - cross

:10:03 1 fine. Right there.

:10:04 2 Okay. So we have CO2 warmer/humidifier and  
:10:08 3 there's a checkmark in the column "Current," and then  
:10:12 4 in the AirSeal column, it says, "Not needed"; is that  
:10:15 5 correct?

:10:16 6 A. Yes, sir.

:10:16 7 Q. Now, the only heater/humidifier that was manufactured  
:10:22 8 in the United States and sold in the United States for  
:10:25 9 heating and humidifying insufflation gas between 2012 and  
:10:30 10 2017 was Lexion's products; is that correct?

:10:33 11 A. I believe so.

:10:34 12 Q. And the purpose of this document is to show customers  
:10:39 13 they can save costs, right, by switching to AirSeal?

:10:42 14 A. For those customers that are using smoke evacuation  
:10:46 15 and CO2 warming and humidifying, about 20 percent of the  
:10:51 16 market uses a smoke evacuator. Probably around one percent  
:10:56 17 uses the Insuflow technology. So this was not a  
:10:58 18 particularly helpful document in those cases.

:11:00 19 Q. All right. But you agreed that this advertisement is  
:11:04 20 targeted towards those who are currently using a CO2  
:11:08 21 warmer/humidifier; right?

:11:09 22 A. This was a single generic document that we used  
:11:12 23 across, you know, hospitals around the country. This was  
:11:14 24 not targeted specifically at any one hospital. This  
:11:19 25 particular example was used because it did show us an

Tegan - cross

:11:22 1 opportunity to save money, but in most cases hospitals would  
:11:25 2 end up not saving money using the AirSeal System, but they  
:11:28 3 chose to pursue it anyway.

:11:30 4 Q. Okay. But you agree, the only person who made a CO2  
:11:34 5 warmer -- sorry. The only company that made a CO2  
:11:37 6 warmer/humidifier was Lexion; right?

:11:39 7 A. Yes, sir.

:11:40 8 Q. So only customers who were using Lexion products  
:11:43 9 currently, as the checkmark indicates, could save money by  
:11:48 10 switching to AirSeal; right?

:11:49 11 A. There were other factors that also affected savings,  
:11:56 12 but for the few customers out there that did use the  
:12:01 13 Airflow, it might be a cost savings in their savings.

:12:07 14 Q. Let me ask Mr. Barnes to put up Lexion Exhibit 34,  
:12:11 15 please. That's the slide.

:12:29 16 THE COURT: Mr. Wille, did you have a cross bind  
:12:31 17 remember you wanted Mr. Tegan to have?

:12:33 18 MR. WILLE: Yes. Actually, Your Honor,  
:12:35 19 permission to approach while Mr. Barnes --

:12:37 20 THE COURT: Yes.

:12:38 21 MR. WILLE: -- finds the slide.

:12:39 22 (Binders handed to the Court and to the  
:12:41 23 witness.)

:13:01 24 MR. WILLE: May I proceed, Your Honor?

:13:04 25 THE COURT: Please.



Tegan - cross

1 BY MR. WILLE:

2 Q. Okay. So on the screen, Mr. Tegan, is Lexion  
3 Exhibit 34. Other witnesses have identified this as coming  
4 from SurgiQuest's website. And there's a statement on the  
5 website, "AirSeal enables you to operate in a clear field  
6 without fear of venting surgical smoke and plume from the  
7 abdominal cavity into the OR suite as the automatic smoke  
8 evacuation function continuously evacuates, filters and  
9 recirculates CO2."

10 Did I read that correctly?

11 A. Yes.

12 Q. And that statement was on SurgiQuest's website for a  
13 number of years; is that correct?

14 A. Yes, it was.

15 Q. Okay. And I think witnesses have testified that this  
16 was in the 2015, early 2015 time frame, but you're aware it  
17 was on there going back to the a least 2013; is that  
18 correct?

19 A. Yes, sir.

20 Q. Let's switch topics. You can take the exhibit down,  
21 Mr. Barnes.

22 SurgiQuest considers Lexion to be a competitor.  
23 Right?

24 A. To a very, very small extent. But, yes.

25 Q. Lexion sells trocars. Right?

Tegan - cross

:15:00 1 A. I am told they sell trocars, yes.

:15:02 2 Q. And SurgiQuest sells trocars. Right?

:15:05 3 A. Yes, we do.

:15:06 4 Q. And it is true that 90 to 95 percent of the tubing  
:15:10 5 sets that SurgiQuest sells for use with the AirSeal system  
:15:13 6 are the ones for the AirSeal trocar. Correct?

:15:16 7 A. Yes, sir. That's why they buy the iFS.

:15:19 8 Q. That's why people buy the iFS, is to use the system in  
:15:23 9 AirSeal mode. Right?

:15:25 10 A. Yes.

:15:25 11 Q. And when the system is used in AirSeal mode, neither  
:15:28 12 the Insuflow or the Synergy trocar can be used with the  
:15:33 13 AirSeal system. Correct?

:15:34 14 A. It is possible. There are certain cases where  
:15:37 15 physicians will hook up a second insufflator, not  
:15:41 16 necessarily with the AirSeal system, but you could  
:15:43 17 technically run two insufflators at the same time if a  
:15:47 18 medical need or clinical need was available or needed.

:15:50 19 Q. But you can't use the Insuflow device or the Synergy  
:15:55 20 trocar with the AirSeal insufflator when it's being used in  
:15:59 21 AirSeal mode. Correct?

:16:01 22 A. That's correct.

:16:01 23 Q. Let's talk about smoke.

:16:09 24 I believe you said on Friday we think it's the  
:16:12 25 best filter out there. Was that your testimony?

Tegan - cross

:16:14 1 A. Yes. I should clarify that. Best particulate filter  
:16:17 2 out there.

:16:18 3 Q. Aren't you aware that some competitors have filters  
:16:21 4 that can filter toxic and carcinogenic gasses out of the  
:16:24 5 smoke?

:16:25 6 A. I believe there are some, yes.

:16:27 7 Q. And, in fact, before acquiring SurgiQuest, ConMed sold  
:16:32 8 smoke evacuators?

:16:34 9 A. I believe, yes.

:16:35 10 Q. And did ConMed smoker evacuators have the ability to  
:16:38 11 filter out toxic and carcinogenic gasses?

:16:41 12 A. I am sorry to say I don't know that.

:16:43 13 Q. Assuming there are competitors that have the ability  
:16:45 14 to filter out toxic and carcinogenic gasses, your filter  
:16:49 15 wouldn't be the best filter then, would it, sir?

:16:51 16 A. Not for those, no.

:16:53 17 Q. Let me ask Mr. Barnes to put up Joint Exhibit 2.

:17:04 18 Do you recognize Joint Exhibit 2?

:17:06 19 A. I do, sir.

:17:07 20 Q. Joint Exhibit 2 is a quarterly newsletter that  
:17:12 21 SurgiQuest put out in June of 2014. Correct?

:17:12 22 A. Yes, sir.

:17:17 23 Q. This newsletter went to customers of SurgiQuest and it  
:17:19 24 was also provided to sales reps. Correct?

:17:22 25 A. Yes. But the newsletter was originally designed

Tegan - cross

:17:24 1 really to be giving information to friends of the family,  
:17:28 2 investors, and more as an internal document. A decision was  
:17:32 3 made at some time to make it available to customers. But it  
:17:38 4 wasn't something we routinely gave out.

:17:40 5 Q. It was made available to customers as of June 2014.  
:17:43 6 Correct?

:17:44 7 A. Yes.

:17:45 8 Q. There is a picture here with a doctor. Right?

:17:49 9 A. Yes.

:17:49 10 Q. And it says, .01 Micron AirSeal Filter, Protect your  
:17:53 11 patient, your Staff and Yourself.

:17:56 12 Right?

:17:56 13 A. Yes, sir.

:17:56 14 Q. That's promoting the safety aspects of smoke  
:18:01 15 evacuation, not visualization within the abdomen, wouldn't  
:18:05 16 you agree?

:18:06 17 A. I would agree that it is promoting reducing risk for  
:18:12 18 particulates, yes.

:18:13 19 Q. One reason that SurgiQuest discusses the evacuation of  
:18:18 20 surgical smoke in promoting its products is keeping the  
:18:21 21 operative field clear so the surgeon can see. Correct?

:18:26 22 A. Absolutely.

:18:26 23 Q. Another reason that has been discussed by your sales  
:18:29 24 reps consistently has also been protecting the safety of  
:18:32 25 those in the operating room. Correct?

Tegan - cross

:18:35 1 A. To a lesser extent, yes.

:18:36 2 Q. Now, you have also trained your sales reps about the  
:18:43 3 dangers of surgical smoke and taught them that the best  
:18:46 4 practice to address those is use of the AirSeal. Right?

:18:52 5 A. In terms of surgical smoke -- I believe we focused  
:18:55 6 more on stable pneumo than we did surgical smoke. But we  
:18:59 7 did mention or did focus that surgical smoke, getting it out  
:19:03 8 of that operative field was essential. And if we can reduce  
:19:06 9 the risk to the people in the operating room, that was a  
:19:09 10 good thing, too.

:19:10 11 Q. You mentioned, sir, isn't it true that you had  
:19:15 12 complete PowerPoint presentations on surgical smoke that you  
:19:18 13 used to train sales reps?

:19:20 14 A. There was for a time. Though I don't know to what  
:19:24 15 extent -- I know they are not actually used in the same way  
:19:29 16 anymore. We have modified our training program to focus  
:19:32 17 primarily on the particulates and the clearance of the  
:19:36 18 abdominal cavity.

:19:37 19 Q. You have modified your focus on particulates because  
:19:41 20 your filter doesn't filter out toxic and carcinogenic  
:19:46 21 gasses. Isn't that correct?

:19:47 22 A. That's true.

:19:47 23 Q. Isn't it true your sales reps were told at one time  
:19:50 24 that the AirSeal is capable of filtering out toxic and  
:19:54 25 carcinogenic gasses?

Tegan - cross

:19:55 1 A. We believe for a time we did. In fact, we were told  
:19:58 2 that was not the case, and we took corrective action, yes.

:20:00 3 Q. Before putting the AirSeal iFS on the market,  
:20:03 4 SurgiQuest did not do any testing to determine whether the  
:20:06 5 filtration system filtered out toxic or carcinogenic gasses  
:20:10 6 in surgical smoke. Correct?

:20:13 7 A. No. We were solely focused on particulates.

:20:15 8 Q. You did not do any testing. Is that right?

:20:19 9 A. Not to my knowledge, although I wasn't around during  
:20:23 10 the development process so I can't say for sure.

:20:25 11 Q. Friday you indicated that you helped to train the  
:20:28 12 sales representatives. Correct?

:20:30 13 A. Yes, sir.

:20:30 14 Q. In fact, you wrote the sales training manual for the  
:20:33 15 AirSeal system. Right?

:20:34 16 A. Yes, sir.

:20:35 17 Q. Another document that you wrote was called the launch  
:20:40 18 guide. Right?

:20:41 19 A. I believe so, yes.

:20:41 20 Q. The launch guide was essentially a sales training  
:20:45 21 manual for the salespersons when the AirSeal iFS was first  
:20:49 22 introduced to the market. Correct?

:20:51 23 A. Yes, sir.

:20:51 24 Q. I think you talked about Friday some competitors  
:21:02 25 saying their product does essentially the same thing as

Tegan - cross

:21:04 1 AirSeal. Correct?

:21:05 2 A. Yes, sir.

:21:05 3 Q. You have heard of competitors doing that. Right?

:21:08 4 A. Yes, sir.

:21:08 5 Q. And, in fact, isn't that the same tactic that you  
:21:12 6 trained the sales reps as to how to sell against Insuflow?

:21:17 7 A. Well, we do have a study that demonstrates that the  
:21:19 8 use of AirSeal causes no reduction in the OR in the humidity  
:21:23 9 of the cavity and less of a reduction in temperature.

:21:27 10 Again, our sales team does not come up against  
:21:31 11 Lexion very often at all. They don't see them in that many  
:21:34 12 hospitals.

:21:34 13 Q. Sir, isn't it true that you trained the sales reps to  
:21:37 14 tell customers that your product did essentially the same  
:21:40 15 thing that the Insuflow device does?

:21:44 16 A. We told them that we maintained relative cavity  
:21:47 17 temperature and that we caused less of a reduction in body  
:21:51 18 temperature.

:21:51 19 Q. Did you train the sales reps to tell customers that  
:21:57 20 the SurgiQuest AirSeal system does essentially the same  
:22:01 21 thing as the Lexion Insuflow device?

:22:04 22 A. To an extent, yes.

:22:06 23 Q. Mr. Barnes, if you could please put up Slide No. 2,  
:22:12 24 please.

:22:17 25 You recognize Lexion Exhibit 6 is the AirSeal

Tegan - cross

:22:21 1 iFS launch guide, the icon on the left there?

:22:24 2 A. Yes.

:22:24 3 Q. And the text here from the launch guide says the good  
:22:30 4 news here is that for those accounts the AirSeal iFS  
:22:33 5 performs essentially the same function. Right?

:22:35 6 A. Yes, sir.

:22:35 7 Q. So it wouldn't shock you if sales reps were out there  
:22:40 8 telling customers what you told them in the launch guide,  
:22:43 9 would it?

:22:44 10 A. It would depend on how they framed their promotion.

:22:50 11 Q. But you wouldn't be surprised if your sales reps told  
:22:54 12 customers that the AirSeal did essentially the same function  
:22:58 13 as the Insuflow. Right?

:22:59 14 A. No, not really.

:23:00 15 Q. In fact, you know they did so, don't you, sir?

:23:04 16 A. I know a few did, yes.

:23:06 17 Q. You also indicate here, Use this financial advantage  
:23:10 18 when selling the AirSeal iFS, AirSeal tubing sets and the  
:23:15 19 AirSeal access port, it will help demonstrate the cost  
:23:18 20 savings for converting to AirSeal for laparoscopic and  
:23:22 21 robotic procedures currently using the Insuflow device.

:23:25 22 Did I read that correctly?

:23:26 23 A. I did, sir.

:23:28 24 Q. That is also something you taught the sales reps to  
:23:31 25 do?



Tegan - cross

:23:32 1 A. Yes, for instance, when they came across Lexion  
:23:36 2 competitors.

:23:36 3 Q. The cost comparison sheet we compared earlier would  
:23:41 4 tell them exactly what you told them to do here in the  
:23:43 5 launch guide. Correct?

:23:44 6 A. One form of it, perhaps, yes.

:23:47 7 Q. Several years later, if we can go to Slide 1, several  
:23:51 8 years later you created the SurgiQuest training manual.  
:23:55 9 Correct?

:23:56 10 A. I believe it was sometime in 2012, late 2012, that's  
:24:01 11 correct, sir.

:24:02 12 Q. That's Joint Exhibit 3. Right?

:24:04 13 A. Yes, sir.

:24:04 14 Q. The sales training manual also continues to train  
:24:11 15 sales reps that the good news here is that for those  
:24:14 16 accounts the AirSeal system performs essentially the same  
:24:16 17 function. Right?

:24:17 18 A. Yes, sir.

:24:17 19 Q. And the financial advantage point is still in the  
:24:19 20 sales training manual. Correct?

:24:22 21 A. Yes, sir.

:24:25 22 Q. But you agree that SurgiQuest never did a head-to-head  
:24:30 23 test against Insuflo to prove that it did substantially the  
:24:34 24 same thing. Correct?

:24:35 25 A. That's correct, we did not.

Tegan - cross

:24:36 1 Q. And SurgiQuest is not aware of any study in a medical  
:24:39 2 journal that compares the Insuflo and AirSeal head-to-head  
:24:44 3 to see if AirSeal does essentially the same thing. Did you?  
:24:50 4 A. No, I am not.  
:24:57 5 Q. I believe you just indicated a few minutes ago that  
:25:01 6 Insuflo wasn't coming up regularly with your sales reps.  
:25:05 7 Is that right?  
:25:06 8 A. Generally speaking, no, it was not the first thing  
:25:09 9 that came up.  
:25:09 10 Q. Mr. Barnes, I would like Lexion Exhibit 191, please.  
:25:20 11 Lexion Exhibit 191, if we can zoom into the top,  
:25:23 12 please, is an e-mail chain between you and Mr. Azarbarzin  
:25:29 13 from April of 2012. Correct?  
:25:32 14 A. Yes, sir.  
:25:32 15 Q. And do you recall this e-mail?  
:25:38 16 A. I do.  
:25:38 17 Q. This is where you received Mr. Stearns's test data.  
:25:42 18 Correct?  
:25:43 19 A. Yes.  
:25:43 20 Q. Mr. Stearns's test was in February of 2012. Right?  
:25:48 21 A. I am not sure of the date, actually. But possibly,  
:25:51 22 yes.  
:25:51 23 Q. This is where you are finding out about it. Right?  
:25:55 24 A. I guess, yes.  
:25:56 25 Q. You say, if we go down below to the second e-mail, you

Tegan - cross

:26:00 1 say, I guess my question was why didn't you let me know  
:26:03 2 about this?

:26:05 3 Do you recall that this is when you learned of  
:26:08 4 Mr. Stearns's test data?

:26:10 5 A. Okay, sure.

:26:10 6 Q. The launch guide, where you told sales reps that  
:26:16 7 SurgiQuest did essentially the same thing as Insuflow, that  
:26:19 8 was created back in 2011, wasn't it?

:26:22 9 A. Late 2011, correct.

:26:24 10 Q. So you told sales reps that the AirSeal did  
:26:27 11 essentially the same thing without doing any testing. Isn't  
:26:31 12 that true?

:26:32 13 A. Yes.

:26:33 14 Q. Now, in this e-mail, you say the information on  
:26:39 15 humidity maintenance is huge. Right? That's how you  
:26:42 16 characterize it. As huge. Right?

:26:46 17 A. I speak emotionally about things.

:26:48 18 Q. And it says it could help back up our claims about not  
:26:52 19 needing the warmer/humidifier anymore. Right?

:26:56 20 A. Yes.

:26:56 21 Q. And you say, This comes up more than you think and  
:27:01 22 Lexion is getting aggressive out there. Right?

:27:04 23 A. Yes, sir.

:27:05 24 Q. Now, you also, the last sentence of your e-mail, you  
:27:14 25 say, The only question would be what are the values long

Tegan - cross

:27:17 1 after five minutes. Right?

:27:20 2 A. Yes, sir.

:27:21 3 Q. Let's go back to Joint Exhibit 1 for a second. Let's  
:27:28 4 go to the bottom of the page, Mr. Barnes. If you can zoom  
:27:31 5 in on the table there.

:27:36 6 Your cost comparison chart indicates for a  
:27:40 7 robotic prostatectomy that the average procedure time is 120  
:27:43 8 minutes, and for a robotic hysterectomy the average  
:27:48 9 procedure time is 90 minutes. Right?

:27:52 10 A. Approximately, yes.

:27:53 11 Q. You would agree, as we sit here today, SurgiQuest has  
:27:56 12 done no test to determine the performance from a heat and  
:28:01 13 humidity perspective of the AirSeal over a 90-minute robotic  
:28:07 14 hysterectomy or a 120-minute prostatectomy. Correct?

:28:12 15 A. Other than the 600,000 procedures without an issue,  
:28:15 16 no, we have not done a test to determine heat and humidity  
:28:18 17 over 90 to 120 minutes.

:28:20 18 Q. The only test SurgiQuest did in its lab was a  
:28:24 19 five-minute test. Isn't that correct?

:28:25 20 A. Yes.

:28:26 21 Q. SurgiQuest has not done a clinical study to compare  
:28:30 22 Insuflow to the AirSeal to see whether they are essentially  
:28:34 23 the same in either the 90-minute robotic hysterectomy where  
:28:38 24 you told people they need the CO2 warmer/humidifier or in a  
:28:43 25 robotic prostatectomy where you told people they didn't need

Tegan - cross

:28:46 1 the CO2 warmer/humidifier. Is that correct?

:28:49 2 A. Well, comparative studies are typically done between a  
:28:52 3 new technology and the standard of care. We found no reason  
:28:55 4 to go out and do a study against the Insuflo system or the  
:29:00 5 Synergy trocar. So, yes, that's correct, no studies.

:28:03 6 Q. Now, you just, I think in your testimony, referred to,  
:28:27 7 you know, having 600,000 procedures without an issue; is  
:28:30 8 that correct?

:28:31 9 A. Without an issue related to heat and humidity that I'm  
:28:35 10 aware, yes.

:28:36 11 Q. Because there have been issues; right?

:28:38 12 A. Every technology has issues. That's correct.

:28:40 13 Q. Subcutaneous emphysema is an issue; right?

:28:43 14 A. It's an issue for all insufflators.

:28:45 15 Q. The pneumothorax is an issue?

:28:47 16 A. As it is for all insufflation systems.

:28:50 17 Q. We'll come back to those.

:28:53 18 Now, let's go back to the e-mail, Mr. Barnes,  
:29:00 19 which is Lexion Exhibit 191.

:29:16 20 When you said this comes up more than you think  
:29:20 21 and Lexion is getting aggressive out there -- when you said  
:29:23 22 this comes up more than you think, what you meant was, it's  
:29:26 23 coming up more than you think with the sales reps out in the  
:29:29 24 field; is that correct?

:29:30 25 A. Yes.

Tegan - cross

1 Q. Okay. And when you say Lexion is getting aggressive  
2 out there, you meant that Lexion was trying to defend its  
3 business; is that correct?

4 A. I don't know --

5 THE COURT: Could I interrupt for just a second?

6 Mr. Barnes, I think actually the jury may be  
7 better able to see it without the highlighting. Yes. The  
8 highlighting is --

9 MR. WILLE: Maybe enlarge the text and remove  
10 the highlighting.

11 THE COURT: Yes; if you can do that. And that  
12 goes for all of these e-mails because of the low light. And  
13 we lose light because of the dome and distance.

14 BY MR. WILLE:

15 Q. All right. Sir, isn't it true that when you say  
16 Lexion is getting aggressive out there, that what you meant  
17 is that Lexion was trying to defend its business; is that  
18 correct?

19 A. I guess so, yes.

20 Q. All right. And you believe that in 2012, you were  
21 hearing that Lexion was telling customers that if someone  
22 wanted the benefits of InsufLOW, they needed to use  
23 InsufLOW; right?

24 A. I believe that that is what Lexion was saying in the  
25 marketplace, yes.

Tegan - cross

:30:35 1 Q. Now, on Friday you talked about an e-mail that  
:30:48 2 Craig Britten had sent out about keeping tissues moist;  
:30:51 3 right?

:30:52 4 A. Yes.

:30:52 5 Q. And you testified he was no longer with the company;  
:30:54 6 is that correct?

:30:55 7 A. That's correct, sir.

:30:56 8 Q. Well, he was -- strike that.

:30:59 9 Mr. Britten was not no longer with the company  
:31:02 10 because he sent that e-mail, was he, sir?

:31:04 11 A. No. Because he was not necessarily very successful as  
:31:08 12 a sales rep.

:31:09 13 Q. Well, all of your sales reps were laid off when the  
:31:11 14 company was sold; isn't that true?

:31:13 15 A. Not at all, sir. ConMed retained, I think, 45 to 55  
:31:17 16 people.

:31:18 17 Q. Okay. And you also pointed out to the jury that the  
:31:21 18 e-mail about keeping tissues moist was right after  
:31:28 19 Mr. Britten was hired; is that correct?

:31:29 20 A. Soon after, yes.

:31:31 21 Q. Were you trying to suggest to the jury that  
:31:34 22 Mr. Britten was a rogue employee and made that up on his  
:31:37 23 own?

:31:37 24 A. What I was suggesting was that reps will often spin  
:31:43 25 information on their own despite guidance from the company,

Tegan - cross

:31:46 1 and one attempt or one thing that reps will typically do is  
:31:50 2 they'll try a shotgun approach. They'll throw all the  
:31:53 3 potential benefits in the hopes that they're receiving, the  
:31:58 4 recipient of the e-mail, a surgeon in this case, that one or  
:32:00 5 two of those benefits would be relevant to that particular  
:32:03 6 surgeon. It's not a very effective means of generating  
:32:06 7 interest. I think that's probably one of the reasons why  
:32:09 8 Craig wasn't necessarily successful. The best way is to  
:32:13 9 engage a physician and find out what's important to him or  
:32:15 10 her.

:32:16 11 Q. Okay. Sir, the jury has heard Mr. Britten's  
:32:26 12 testimony. If Mr. Britten testified that he got those  
:32:29 13 bullet points from his sales manager at SurgiQuest, would  
:32:32 14 you have any reason to dispute him?

:32:33 15 A. I guess not, but the manager certainly wasn't given  
:32:43 16 that direction by the company.

:32:44 17 MR. WILLE: Okay. Mr. Barnes, would you please  
:32:45 18 put up Lexion Exhibit 51, please.

:32:50 19 BY MR. WILLE:

:32:53 20 Q. Sir, these are a set of preliminary customer  
:32:56 21 requirements; is that correct?

:32:57 22 A. Yes, sir.

:32:59 23 Q. And you drafted this document; right?

:33:01 24 A. I did.

:33:02 25 Q. Your best recollection is that you drafted it in late



Tegan - cross

:33:05 1 2013, early 2014; is that correct?

:33:08 2 A. Yes.

:33:09 3 Q. Customer requirements are initial design  
:33:13 4 considerations based upon customer feedback that you  
:33:15 5 received; is that correct?

:33:16 6 A. Yes, sir.

:33:18 7 Q. And one of the things that's listed in the preliminary  
:33:20 8 requirements is a list of new product features; is that  
:33:23 9 correct?

:33:24 10 A. Yes.

:33:24 11 Q. All right. And isn't it true that one of the features  
:33:28 12 that you identified in late 2013 and early 2014 as highly  
:33:35 13 desirable was active humidification?

:33:37 14 A. That would be for smoke evacuation mode and standard  
:33:41 15 insufflation mode, yes, because there's no recirculation.  
:33:45 16 Recirculation doesn't work in that regard. It's not  
:33:48 17 AirSeal. So, yes, we wanted to add that so that we could,  
:33:51 18 you know, be well accepted by everybody, not just 90-plus  
:33:56 19 percent of the marketplace.

:33:57 20 Q. And that was based upon customer feedback that you  
:34:01 21 received, that people wanted active humidification; is that  
:34:04 22 correct?

:34:04 23 A. I don't know that it was based on feedback from any  
:34:07 24 physicians, but a good marketing person is always out in the  
:34:12 25 field. They are trying to identify ways to broaden their

Tegan - cross

:34:14 1 business, and if there was a subset of physicians that we  
:34:17 2 could not get to because they wanted humidification done  
:34:22 3 actively, then it made sense to be able to add that to our  
:34:25 4 device in the future.

:34:26 5 Q. Okay. Now, on Friday --

:34:29 6 MR. WILLE: You can take that one down,  
:34:31 7 Mr. Barnes.

:34:31 8 BY MR. WILLE:

:34:31 9 Q. On Friday you talked about the instructions for use,  
:34:34 10 and the jury has heard a lot about these instructions for  
:34:36 11 use. I don't need to get those out for you, do I?

:34:39 12 A. No.

:34:39 13 Q. You know what I'm talking about. All right.

:34:41 14 So now at some point, Stryker Corporation, one  
:34:46 15 of their sales reps showed those instructions for use to a  
:34:49 16 doctor in Florida; is that right?

:34:51 17 A. That's correct.

:34:52 18 Q. And the doctor in Florida had some concern and  
:34:55 19 contacted SurgiQuest about those instructions; is that  
:34:58 20 correct?

:34:59 21 A. Yes. I took the phone call, actually.

:35:01 22 Q. Okay. And you created a letter to send back to the  
:35:06 23 doctor; is that correct?

:35:07 24 A. Yes, sir.

:35:08 25 Q. And that letter was turned into a standard letter that

Tegan - cross

:35:11 1 could be sent to anyone that inquired about air entrainment;  
:35:16 2 is that correct?

:35:17 3 A. Yes. It didn't happen often, but if it came up, the  
:35:19 4 letter was drafted to that particular physician, yes.

:35:22 5 MR. WILLE: Mr. Barnes, can we have Lexion  
:35:24 6 Exhibit 244, please. And zoom in on the first paragraph,  
:35:32 7 please.

:35:35 8 BY MR. WILLE:

:35:36 9 Q. And your letter says, "It has come to SurgiQuest's  
:35:38 10 attention that some of your, quote, 'competitors,' unquote,  
:35:41 11 have been engaging in sales theatrics by showing some  
:35:45 12 language in the instructions for use booklet for the AirSeal  
:35:49 13 System in an attempt to dissuade you from using what has  
:35:52 14 become the standard of care for many surgeons around the  
:35:55 15 globe."

:35:56 16 Did I read that correctly?

:35:57 17 A. Yes, sir.

:35:58 18 Q. Okay. So when somebody pointed out that the  
:36:01 19 instructions for use indicated air entrainment and they  
:36:05 20 said, gee, I might have some concern about this, you told  
:36:07 21 them that was just sales theatrics; is that right?

:36:09 22 A. It was a little more context here. The Stryker  
:36:14 23 representative said, shouldn't you be concerned about  
:36:16 24 infection or things like that? So theatrics is the adding  
:36:20 25 of hypothetical theoretical things that have not shown up.

Tegan - cross

:36:25 1 So, yes. In that regard, I would say there was a theatrical  
:36:29 2 performance by the Stryker representative and perhaps some  
:36:33 3 others.

:36:33 4 Q. Okay. Well, sir, the jury has seen evidence that Dr.  
:36:37 5 Danielewicz told SurgiQuest in 2007 that infection risk is  
:36:43 6 reduced in a pure carbon dioxide environment. Did  
:36:46 7 SurgiQuest ever go test whether or not there was an  
:36:48 8 increased infection rate with the AirSeal?

:36:50 9 A. Not to my knowledge, no.

:36:52 10 Q. Okay. Now, let's go down to the bottom of the letter,  
:36:55 11 the bottom of this middle paragraph here.

:36:58 12 The last sentence states: "The AirSeal IFS with  
:37:02 13 its proprietary gas sensor and flow capabilities addresses  
:37:07 14 this common issues and ensures that optimal CO2  
:37:12 15 concentration is achieved not only during initial  
:37:16 16 insufflation, but throughout the procedure as well." Is  
:37:18 17 that correct?

:37:18 18 A. Yes.

:37:19 19 Q. And that's false, isn't it?

:37:23 20 A. I don't know how it's false.

:37:23 21 Q. Well, optimal CO2 concentration is close to a hundred  
:37:28 22 percent CO2, isn't it, sir?

:37:31 23 A. I'm not sure of the exact statistics, but presumably  
:37:33 24 it's north of 90, yes.

:37:34 25 Q. All right. We looked at that cost comparison chart

Tegan - cross

:37:37 1 earlier?

:37:37 2 A. Yes.

:37:38 3 Q. Do you remember that?

:37:39 4 A. Yes.

:37:39 5 Q. All right. And one of the things it says you can  
:37:41 6 eliminate there is an occluder for a hysterectomy; is that  
:37:45 7 correct?

:37:45 8 A. That's correct.

:37:46 9 Q. All right. And, sir, you know that if an occluder is  
:37:49 10 not used during hysterectomy for many minutes, a large  
:37:51 11 amount of air is going to be sucked into the abdomen using  
:37:54 12 AirSeal; isn't that right?

:37:55 13 A. Actually, I don't know that. What typically happens  
:37:58 14 is the physician assistant would use a glove or a folded  
:38:04 15 piece of gauze, place that into the vagina to prevent gas  
:38:08 16 leakage. Sometimes when they don't do that, there's a  
:38:12 17 fluttering and that can make it difficult for the surgeon to  
:38:16 18 sew the vaginal cuff closed. So nine times out of ten,  
:38:21 19 people are putting something in the vagina to prevent the  
:38:25 20 gas leakage.

:38:27 21 Q. Well, now, sir, the jury has seen video by Dwight Im  
:38:33 22 with the SurgiQuest trademark on it?

:38:36 23 A. Yes.

:38:36 24 Q. Do you remember that video?

:38:37 25 A. Yes.

Tegan - cross

:38:37 1 Q. And Dwight Im advertises using the hysterectomy with  
:38:41 2 the vaginal cuff wide open?

:38:43 3 A. He does.

:38:43 4 Q. And you know surgeons do that with the AirSeal System;  
:38:46 5 right?

:38:46 6 A. A few perhaps, yes.

:38:48 7 Q. Now, so if surgeons do that, you would agree that the  
:38:54 8 optimal CO2 concentration is not achieved throughout the  
:38:57 9 procedure; right?

:38:58 10 A. No. Once the vaginal cuff is closed or the  
:39:03 11 significant leak is stopped, CO2 concentration rises to the  
:39:06 12 level again.

:39:06 13 Q. But while the leak is there, the CO2 concentration is  
:39:12 14 not optimal. Wouldn't you agree?

:39:15 15 A. Yes.

:39:15 16 Q. Okay. And SurgiQuest has no understanding of the  
:39:22 17 maximum percentage of air that is drawn into the abdomen  
:39:25 18 when a hysterectomy is done without an occluder; is that  
:39:30 19 correct?

:39:30 20 A. That's correct.

:39:31 21 Q. All right. Let's go back to subcutaneous emphysema.

:39:33 22 You agree there are medical journal articles  
:39:36 23 that report higher rates of subcutaneous emphysema in  
:39:40 24 studies involving the AirSeal versus conventional  
:39:44 25 insufflators; is that correct?

Tegan - cross

1 A. I have an issue with that, only that the comparison.  
2 So there's one journal article in particular that focuses on  
3 the very lowest ranges of subcutaneous emphysema  
4 complication rates. And the five journals, journal articles  
5 with AirSeal where that happened, four of which were done in  
6 urology procedures.

7 Now, urology, laparoscopic urology, has a much  
8 higher rate of things like subcutaneous emphysema and  
9 pneumomediastinum and pneumothorax, and I believe it was  
10 intellectually dishonest for the author of that paper to  
11 compare our statistics in laparoscopic urology versus simple  
12 gall bladders and simple abdominal procedures.

13 Q. Sir, I didn't ask you about comparing statistics. I  
14 asked you whether there were papers where conventional  
15 insufflators were used for one group of patients, the  
16 AirSeal was used for another group of patients, and you had  
17 higher rates of subcutaneous emphysema when AirSeal was  
18 used; isn't that true?

19 A. Yes.

20 Q. Okay. And, in fact, SurgiQuest was so concerned about  
21 subcutaneous emphysema, that it reported to the Board of  
22 Directors, didn't it?

23 A. At one point, yes.

24 Q. You did that report; right?

25 A. I believe so.

Tegan - cross

1 Q. Okay. Let's put up Lexion Exhibit 163. Board of  
2 Directors meeting, July 25th, 2013.

3 Was this the meeting where you reported to the  
4 Board of Directors on subcutaneous emphysema?

5 A. I guess so, yes.

6 Q. Okay. And I mean, I can show you the slides if you  
7 want me to, but --

8 A. I tack your word for it.

9 Q. Yes. The slide here says slide 45, subcutaneous  
10 emphysema in laparoscopy. You gave a report to the  
11 SurgiQuest Board of Directors; is that right?

12 A. That's correct.

13 Q. And that was not because of something Lexion did. It  
14 was because SurgiQuest had received reports or inquiries  
15 about subcutaneous emphysema from surgeons; right?

16 A. I this it was more focused on the literature. Dr.  
17 Herati's articles, the Selik article, which came out some  
18 time in 2013, and a few surgeon comments as well.

19 Q. Sir, isn't it true that SurgiQuest had received  
20 inquiries about subcutaneous emphysema from surgeons  
21 independent of Lexion making surgeons aware of the  
22 complications?

23 A. Yes.

24 Q. All right. And it is also true that the decision to  
25 address the issue of subcutaneous emphysema was not related



Tegan - cross

1 to what Lexion was doing in the marketplace; is that true?

2 A. Not solely related to what Lexion was doing in the  
3 marketplace. As a company, if there was a perception out  
4 there that we were doing something worse, something that was  
5 hurting patients, we wanted to get to the bottom of it, and  
6 we did.

7 Q. Okay. Let me ask Mr. Barnes to put up Lexion  
8 Exhibit 184.

9 And Lexion Exhibit 184 is an e-mail chain from  
10 October 2012; is that correct?

11 A. Yes.

12 Q. All right. And down, if we go down the page, you sent  
13 an e-mail October 25th, 2012, to Mr. Azarbarzin; is that  
14 correct?

15 A. Yes, sir.

16 Q. Okay. And one of the comments that you make, comment  
17 number 5, is, I don't think this would have been any  
18 different with the IFS because it has to do with how the  
19 system functions.

20 Perhaps the message excessive leakage would have  
21 shown up for a brief moment, but we both know it probably  
22 wouldn't be noticed or -- would be noticed or regarded once  
23 it stopped.

24 Did I read that correctly?

25 A. Yes. It was before the statement written by myself.

Tegan - cross

:43:37 1 Q. Okay. But the statement that you're referring to here  
:43:39 2 in the paper, this is a paper that used DPS?

:43:42 3 A. I believe so, yes.

:43:44 4 Q. Okay. Can you go down -- sorry. Let me ask you about  
:43:55 5 comment number 6.

:43:56 6 Comment number 6 says, "I think having him  
:44:00 7 continue to publish with the IFS makes sense, but I don't  
:44:03 8 think we should dismiss this by saying it was done with the  
:44:05 9 old technology. Doing so would hurt our ability to use the  
:44:10 10 time savings and CO2 absorption data that we used all the  
:44:15 11 time."

:44:16 12 Did I read that correctly?

:44:17 13 A. Yes.

:44:17 14 Q. What you are saying there is we shouldn't dismiss this  
:44:22 15 paper with customers by saying it was done with the DPS  
:44:24 16 because we're using clinical data from the DPS to try to  
:44:28 17 sell the IPS?

:44:29 18 A. That's correct.

:44:30 19 Q. All right. Now, Friday you testified that you don't  
:44:32 20 think surgeons care if air is going into the abdomen,  
:44:36 21 because there can be some air trapped in the tubing set when  
:44:38 22 the procedure begins.

:44:40 23 Do you remember that?

:44:41 24 A. Yes.

:44:42 25 Q. Okay. And I think you said that's about a third of a

Tegan - cross

:44:48 1 liter of air?

:44:48 2 A. It could be up to a third of a liter of air.

:44:51 3 Q. Let's make sure the jury understands what you are  
:44:52 4 saying. The tubing set goes from the insufflator, the  
:44:55 5 AirSeal insufflator, to the trocar; right?

:44:58 6 A. Ten feet.

:44:58 7 Q. Ten feet. Right. So there's ten feet of tubing?

:45:01 8 A. Yes.

:45:01 9 Q. Now, what you are saying is, before you start to  
:45:04 10 flow carbon dioxide, there's air trapped in there; is that  
:45:07 11 right?

:45:07 12 A. Air also a little bit in the trocar and probably some  
:45:12 13 in the box before the valve opens to let the gas goes out.

:45:15 14 Q. All right. And you said the total of gas is about a  
:45:17 15 third of a liter?

:45:18 16 A. Yes.

:45:18 17 Q. And the average abdomen is two to three liters in  
:45:22 18 size; right?

:45:22 19 A. That's correct.

:45:23 20 Q. All right. So about one-sixth to one-ninth of the  
:45:25 21 gas that's in there once the abdomen is inflated, assuming  
:45:28 22 all the air stays in there, is air; right?

:45:30 23 A. Yes.

:45:31 24 Q. Okay. And that's somewhere between, if I do the math,  
:45:34 25 between 80 and 90 percent; right?

Tegan - cross

:45:36 1 A. 80 and 90 percent?

:45:38 2 Q. It's 80 to 90 percent CO2?

:45:40 3 A. Yes.

:45:41 4 Q. Okay. So when the CO2 starts to flow, that entrapped

:45:45 5 air that's in the tubing flows into the abdomen. That's

:45:48 6 what you are saying; right?

:45:49 7 A. Yes, sir.

:45:49 8 Q. Okay. And your belief was that surgeons should not

:45:55 9 care about air in the abdomen because air in the tubing set,

:45:59 10 when the procedure gets into the abdomen; right?

:46:01 11 A. I didn't say what they should or shouldn't care about.

:46:04 12 I said that they clearly didn't care about it or it was --

:46:09 13 their actions demonstrated that they weren't concerned about

:46:11 14 getting air into the abdomen.

:46:13 15 Q. So, sir, did you rethink that testimony perhaps over

:46:17 16 the weekend?

:46:18 17 A. No.

:46:18 18 Q. No desire to change that testimony?

:46:20 19 A. No, sir.

:46:21 20 Q. All right. Isn't it true that the tubing set, the air

:46:24 21 in the tubing set can present a safety issue for the

:46:27 22 patient?

:46:27 23 A. I'm not sure how.

:46:30 24 Q. Well, aren't surgeons trained to start the CO2 flow

:46:34 25 and prime the tubing set with CO2 before connecting it to

Tegan - cross

:46:38 1 the abdomen?

:46:39 2 A. I'm not an expert on surgeon training. I don't know.

:46:42 3 They may have been taught that long ago. What they do in a

:46:46 4 day-to-day practice is very difficult.

:46:47 5 Q. Sort of like when a nurse primes the needle, a

:46:50 6 syringe, and squirts a little out to make sure that there's

:46:53 7 liquid in the syringe; right?

:46:55 8 A. Yes.

:46:56 9 Q. Okay. That's priming.

:46:58 10 So aren't surgeons trained to prime the tubing

:47:01 11 set to protect the safety of the patient?

:47:03 12 A. Again, I'm not sure if they are trained that way or

:47:07 13 not. If they were, they're currently not doing it very

:47:09 14 often at all.

:47:11 15 Q. Now, you train sales reps; right?

:47:14 16 A. Yes.

:47:14 17 Q. As part of your job as training sales reps, do you

:47:19 18 have the responsibility to read the instruction manuals that

:47:22 19 SurgiQuest publishes?

:47:23 20 A. The IFS user manual?

:48:12 21 Q. Yeah.

:48:13 22 A. I don't know that I read it cover to cover.

:48:15 23 Q. Let's put up Joint Exhibit 4. Let's put up the cover.

:48:20 24 This is the user manual for the iFS. Correct?

:48:24 25 A. Yes, one version of it, yes.

Tegan - cross

1 Q. And, Mr. Barnes, if you would turn to the page with  
2 Bates label LEX 5828. I would like you to zoom in toward  
3 the causation statement that's towards the bottom of the  
4 page.

5 Sir, what this says is, for the safety of the  
6 patient, please fill the tube set with CO2 gas prior to  
7 beginning the insufflation by activating the insufflation  
8 for a few seconds and then turning it off again before  
9 introducing the insufflation instrument to the abdomen and  
10 beginning the surgery.

11 Did I read that correctly?

12 A. Yes, you did.

13 Q. That's priming the tube set with CO2 like we were  
14 discussing. Correct?

15 A. Yes.

16 Q. And it says, you do that for the safety of the  
17 patient. Correct?

18 A. Yes. This was language borrowed from World of  
19 Medicine, who manufactures our insufflation system and that  
20 of the Stryker pneumo system which you have seen and heard  
21 about.

22 Q. A minute ago we agreed that the amount of CO2 -- the  
23 amount of CO2 in the abdomen even if all the air went into  
24 the abdomen and none of it escaped was between 80 percent  
25 and 90 percent CO2 concentration. Right?

Tegan - redirect

:49:42 1 A. Yes.

:49:42 2 Q. Yet that amount of air in the abdomen, SurgiQuest  
:49:46 3 teaches its customers here, could have an issue for the  
:49:49 4 safety of the patient. Isn't that true, sir?

:49:51 5 A. That's what it states, yes.

:49:55 6 MR. WILLE: No further questions, Your Honor.

:49:57 7 THE COURT: All right. Your redirect.

:49:59 8 MR. RYAN: Thank you, Your Honor.

:50:01 9 REDIRECT EXAMINATION

:50:01 10 BY MR. RYAN:

:50:02 11 Q. Mr. Tegan, I would like to stay on this topic of air,  
:50:05 12 please.

:50:05 13 A. Yes, sir.

:50:09 14 Q. How many procedures have been performed with the  
:50:12 15 AirSeal system now?

:50:13 16 A. Well over 600,000.

:50:14 17 Q. How many surgeons have told you or SurgiQuest that  
:50:19 18 they are concerned about air getting into the abdomen?

:50:21 19 A. None, to my knowledge.

:50:28 20 Q. You were asked questions about subcutaneous emphysema.  
:50:32 21 Again, how many surgeons have complained to SurgiQuest about  
:50:37 22 subcutaneous emphysema?

:50:39 23 A. A couple dozen, perhaps.

:50:40 24 Q. And are you aware whether or not subcutaneous  
:50:44 25 emphysema occurs with other insufflators?

Tegan - redirect

:50:46 1 A. It does.

:50:46 2 Q. Is that just part of the technology for insufflation?

:50:50 3 A. Yes. So basically, when you pressurize the abdomen  
:50:53 4 with gas, that gas is going to try and find a way to get to  
:50:58 5 a lower pressure area. It's kind of like if you have a lot  
:51:01 6 of water in your bathtub and there is a crack in the  
:51:04 7 bathtub, the water is going to find its way out. That is  
:51:07 8 one of the ways subcutaneous emphysema happens. Another way  
:51:10 9 is sometimes --

:51:11 10 MR. WILLE: Your Honor, objection. When I was  
:51:13 11 cross-examining I think he said he is not a surgeon. Now he  
:51:16 12 is trying to explain what a surgeon knows.

:51:19 13 MR. RYAN: I asked him a question regarding  
:51:22 14 whether it happens in other insufflation technologies. He  
:51:25 15 is simply explaining the answer.

:51:27 16 THE COURT: You don't think he can explain the  
:51:27 17 physiology?

:51:32 18 MR. WILLE: He told me he couldn't.

:51:33 19 THE COURT: Let the jury decide what they want.

:51:37 20 MR. WILLE: Thank you, Your Honor.

:51:39 21 BY MR. RYAN:

:51:40 22 Q. Please continue.

:51:41 23 A. So this can happen with insufflation systems. Now,  
:51:44 24 sometimes they do what's called extraperitoneal or  
:51:47 25 retroperitoneal surgery. And that involves surgery outside



Tegan - redirect

1 the abdomen. This often happens in kidney surgery where  
2 they go into the abdomen, they peel down the peritoneum and  
3 they operate behind the peritoneum. So you are already  
4 dropping that barrier that prevents the gas from getting  
5 inside the peritoneal cavity outside the peritoneal cavity.

6 It is far more common in kidney surgery and  
7 other types of surgery.

8 Q. Mr. Tegan, have any gynecologists complained about air  
9 getting into the abdomen during hysterectomies?

10 A. Not to my knowledge, no.

11 Q. Mr. Wille was asking you questions about the  
12 importance of heat and humidification. Let me ask you a few  
13 questions.

14 In the marketplace, how many surgeons are  
15 demanding heat and humidification in relation to the AirSeal  
16 system?

17 A. I am sorry?

18 Q. Are surgeons demanding heat and humidification for the  
19 AirSeal system?

20 A. No.

21 Q. How many insufflator systems provide heat and  
22 humidification?

23 A. To my knowledge, there is no single insufflation  
24 system that provides active heat and humidification.

25 Q. Would you tell the jury what the market share is for

Tegan - redirect

:52:57 1 the AirSeal system compared to the largest competitors in  
:53:00 2 the marketplace for insufflators?

:53:02 3 A. Sure. So the AirSeal system has about 6 percent  
:53:06 4 market share. The two largest competitors are Stryker and  
:53:10 5 Carl Storz. Between the two of them they probably have 75  
:53:15 6 to 80 percent market share.

:53:18 7 Q. How are they able to sell their insufflators if they  
:53:21 8 don't provide heat and humidification?

:53:24 9 A. Perhaps it's not needed.

:53:34 10 Q. Mr. Tegan, if you understood that a salesperson was  
:53:37 11 making representations about a product that were  
:53:39 12 inconsistent with the way you wanted the product to be  
:53:43 13 marketed, what would you do?

:53:45 14 A. I would tell them to stop.

:53:47 15 Q. Has that happened before?

:53:49 16 A. Yes.

:53:51 17 Q. Tell the jury what you do in those circumstances?

:53:54 18 A. Well, we speak to the rep. If we believe the rep was  
:53:58 19 doing something or that other people were doing something,  
:54:03 20 typically, at SurgiQuest, we would have weekly conference  
:54:06 21 calls with the entire sales organization. When we had like  
:54:09 22 6 to 12, that was easy. When we had like 40 to 50, it  
:54:14 23 became somewhat problematic.

:54:15 24 We would make an announcement typically during  
:54:17 25 the sales call, it would be a, you know, what is your

Tegan - redirect

1 number, what do you have in the pipeline? Marketing would  
2 come in and say, this, this, this, you are doing well, we  
3 need you to cease and desist this, this, and this.

4 Usually, there wasn't that much stuff we had to  
5 counsel them on. We wanted to make sure they always  
6 understood what were the benefits we were selling and what  
7 to avoid talking about.

8 Q. Mr. Wille asked you a question regarding your  
9 impression in February of 2012 about heat and humidity. I  
10 think he was focused on the word huge. Is that correct?

11 A. Yes.

12 Q. Has SurgiQuest learned things about what robotic  
13 surgeons want in the marketplace since 2012?

14 A. Yes.

15 Q. Tell the jury what they have learned regarding heat  
16 and humidification or any other feature?

17 A. Robotic surgeons tell us that the stable pneumo --  
18 many surgeons have called the iFS the greatest thing that  
19 happened to laparoscopy since the robot.

20 Stable pneumo means the world to them. Being  
21 able to see the procedure while they are operating means the  
22 world to them. Two reasons surgeons buy the AirSeal system  
23 are for the visibility and the exposure, the constant  
24 pneumo. That's what matters to them.

25 Q. Do you continue to -- you continue to have

Tegan - redirect

:55:36 1 communications with robotic surgeons regarding what they  
:55:40 2 want insofar as their minimally invasive surgery?

:55:42 3 A. We do.

:55:44 4 Q. And today, what's your assessment as to whether or not  
:55:49 5 surgeons are interested in heat and humidification for  
:55:53 6 minimally invasive surgery?

:55:54 7 A. It's not something we hear at all.

:56:05 8 Q. You testified that there have been 600,000 procedures  
:56:11 9 approximately performed to date. In any of those  
:56:14 10 procedures, as a result of those procedures, have any  
:56:16 11 surgeons come back to you and said we really need heat and  
:56:20 12 humidification in this product?

:56:22 13 A. No.

:56:25 14 Q. Let me talk to you about smoke. You were asked a lot  
:56:29 15 of questions about smoke. Does Lexion have a product in  
:56:34 16 this case that removes smoke, as far as you are concerned,  
:56:38 17 as far as you are aware?

:56:38 18 A. I believe they do.

:56:39 19 Q. Are they selling that product now?

:56:41 20 A. I believe it's available for sale, yes.

:56:43 21 Q. How is it selling, do you know?

:56:45 22 A. I don't know that I have seen it in the course of my  
:56:48 23 travels in operating rooms. I don't know how much they are  
:56:51 24 selling.

:56:51 25 Q. How many surgeries have you observed?

Tegan - redirect

:56:56 1 A. Since the beginning of my career, well over a  
:56:59 2 thousand. Probably several hundred in the last five or six  
:57:02 3 years.

:57:02 4 Q. How many of those surgeries use some type of smoke  
:57:05 5 evacuator that removes operating room smoke of the thousand  
:57:09 6 you have observed?

:57:12 7 A. 20 to 25 percent, maybe. It's not a lot of people  
:57:16 8 that are using smoke evacuators. They will typically open a  
:57:19 9 trocar, if it gets too smoky, vent the gas into the room.

:57:30 10 Q. You were also asked questions about surgeons priming  
:57:34 11 the tube set before engaging the AirSeal system. Do you  
:57:38 12 recall that?

:57:38 13 A. Yes.

:57:39 14 Q. How many procedures have you observed with the AirSeal  
:57:44 15 system?

:57:46 16 A. Several hundred at this point.

:57:47 17 Q. Do surgeons prime the AirSeal system?

:57:50 18 A. No.

:58:10 19 MR. RYAN: Thank you, Your Honor. Nothing  
:58:11 20 further.

:58:12 21 THE COURT: Thank you, sir. Please be careful  
:58:15 22 stepping down.

:58:15 23 (Witness excused.)

:58:17 24 THE COURT: All right.

:58:18 25 MR. RYAN: Your Honor, SurgiQuest calls John

Tegan - redirect

1 Collins.

2 ... JOHN M. COLLINS, having been duly sworn as a  
3 witness, was examined and testified as follows ...

4 MS. PASCAL: Thank you, Your Honor. If I may  
5 just approach with the binders.

6 DIRECT EXAMINATION

7 BY MS. PASCAL:

8 Q. Good morning, Dr. Collins.

9 A. Good morning.

10 Q. What is your profession?

11 A. Mechanical engineer.

12 Q. How long have you been a mechanical engineer?

13 A. My parents would say when I was born. Formally, I  
14 have been practicing for about 30 years.

15 Q. What degrees do you have hold?

16 A. I got a Bachelor's degree from RPI, Rensselaer  
17 Polytechnic Institute, in Upstate New York, and I got a  
18 Master's in chemical engineering from MIT, as well as a  
19 Ph.D. in chemical engineering from MIT.

20 Q. Where do you currently work?

21 A. I work in an organization called CIMIT, it stands for  
22 Consortium for Improving Method for Innovation and  
23 Technology. It is a nonprofit consortium made up of  
24 hospitals and universities in Boston founded about 20 years  
25 by Mass General Hospital, Brigham & Women's Hospital, and

Collins - direct

MIT and Cambridge. It has now evolved into 13 institutions in Boston hospitals, teaching hospitals, and a number of affiliates across the U.S. and the globe.

Q. Do you work anywhere else?

A. Yes. I have a small consulting firm that I work at.

Q. What experience do you have with medical devices?

A. Well, I have been working, my academic career was involved in biochemical applications, both my Master's thesis and my Ph.D. thesis. Since joining the work force I have worked on quite a number of medical devices.

Q. Can you briefly tell us what types of medical devices you have worked on typically with relevance to this case?

A. Certainly, you have heard a lot about the traditional trocars. One of the first projects was I worked with Ethicon in developing their mechanical sealed trocars. Also, things called the Lorange (phonetic) or irrigation pumps that are used in surgery to wash tissue. And we developed a product for Stryker's orthopedic applications, for Bausch & Lomb for irrigating the eye during eye surgeries.

Those are all using a particular pump called a scroll pump which we also use for blood. And from a blood perspective, developed a blood flow warmer. These are devices you have heard about, bear-huggers and the other things, to keep the patient's body temperature warm during

Collins - direct

:02:04 1 surgery. You heat up, if there is blood being infused, or  
:02:09 2 liquids being confused, you heat it up before putting it  
:02:13 3 into bodies.

:02:14 4 Those are some examples.

:02:15 5 Q. Are you an inventor on any patents?

:02:18 6 A. I hold about 20 U.S. patents.

:02:21 7 Q. Do any of those relate to medical devices?

:02:24 8 A. Yes, about half.

:02:27 9 MS. PASCAL: Your Honor, we offer Dr. Collins as  
:02:30 10 an expert in engineering in the field of medical devices.

:02:32 11 THE COURT: Mr. Wille, any objection?

:02:34 12 MR. WILLE: No objection, Your Honor.

:02:36 13 THE COURT: The doctor is accepted as an expert  
:02:39 14 in that field.

:02:41 15 BY. MS. PASCAL:

:02:41 16 Q. Dr. Collins, prior to your involvement in this  
:02:44 17 litigation, did you have a relationship with SurgiQuest?

:02:45 18 A. No, I did not.

:02:46 19 Q. Are you being compensated for your time spent on this  
:02:49 20 case?

:02:49 21 A. Yes, I am.

:02:50 22 Q. At what amount?

:02:51 23 A. At \$400 per hour.

:02:54 24 Q. Can you briefly tell us what your assignment for this  
:02:56 25 case was?



Collins - direct

:02:57 1 A. Sure. My assignment was to basically look at the  
:02:59 2 issues from a technical perspective, and to be able to  
:03:03 3 respond to the report that Dr. Burban had on the technical  
:03:08 4 issues, primarily the air, the CO2 air concentration, the  
:03:11 5 heat and humidity, and smoke.

:03:14 6 Q. Did you put together a set of slides to help  
:03:17 7 illustrate your analyses?

:03:18 8 A. I did.

:03:19 9 Q. Mr. Splansky, if we could go to Slide 3.

:03:22 10 Just to start us off, can you briefly orient us  
:03:26 11 to what is shown on this slide?

:03:28 12 A. I think you are all probably familiar with this. This  
:03:30 13 is the AirSeal system that's composed of the three elements,  
:03:34 14 the access port that sits on the abdominal wall, the AirSeal  
:03:39 15 insufflator that provides the CO2, and the lumen or tube set  
:03:43 16 that connects the two.

:03:45 17 Q. With respect to this port shown on the right side, did  
:03:49 18 you make an analysis of how it functions?

:03:52 19 A. Yes. I looked at the device to understand how it  
:03:58 20 works.

:04:00 21 Q. If we could go to the next slide, Mr. Splansky, if you  
:04:04 22 would.

:04:04 23 Dr. Collins, can you tell us what's shown here?

:04:06 24 A. Sure. This is a cutaway view of the AirSeal access  
:04:13 25 port. So literally it is taking the AirSeal, cutting it

Collins - direct

1 right down in half and looking at it.

2 What you can see here is, this is the area where  
3 the tube set connects and there are a bunch of passages in  
4 the area. Right through here, this whole blue area is all  
5 open, that is air you can pass through or takes samples of.

6 Q. If we could go to Slide 8, Mr. Splansky.

7 Dr. Collins, what are we looking at here?

8 A. Kind of stepping through how this works, this is all  
9 happening at the same time, I will build it one step at a  
10 time, once of these lumens, is a continuous flow of CO2 into  
11 the abdominal cavity at nominally 3 or 8 liters per minute.

12 Q. And if we could go to slide nine, Mr. Splanski.

13 And what is represented by this slide, Dr.  
14 Collins?

15 A. So this is the, what's called high pressure  
16 recirculation line. So this is coming out of the pump,  
17 bringing high pressure gas. And there's an annular space  
18 here, and that annular space is pressurized with gas, and  
19 that gas goes through the orifices and jets come out. It's  
20 really, if you will, the magic of what has happened in this  
21 particular product, because as those jets go down, it  
22 basically creates that air barrier. Kind of the phenomenon  
23 would be much like if you were driving down the street, down  
24 the highway and you put your hand out the window, you will  
25 feel the air pressure on your hand. That's exactly what has

Collins - direct

:04:54 1 happened here. The jets are coming in at a high speed.

:04:57 2 They hit the other gasses. They slow down, and when they

:05:00 3 slow down, that transfers the momentum to the gas and that

:05:03 4 creates that back pressure.

:05:05 5 Q. Dr. Collins, before we move on to the next slide, I

:05:08 6 wanted to ask you one more thing about the carbon dioxide

:05:10 7 flow that you showed us in the earlier slide, but is shown

:05:14 8 here as well.

:05:14 9 Does this flow, you say continuously. Is that

:05:17 10 throughout the surgery?

:05:18 11 A. Yes. It's flowing continuously. With that said, it

:05:23 12 is interrupted briefly each second because that same channel

:05:26 13 is used to measure the pressure in the abdominal cavity.

:05:31 14 So if you have the air flow or the gas, CO2 flowing in, that

:05:34 15 would interrupt or cause air to maintain the pressure. So

:05:39 16 it stops for a brief period, pressure is measured, and then

:05:43 17 the flow is measured. It's only a fraction of a second. It

:05:47 18 is what is happening throughout the entire procedure.

:05:49 19 Q. And that stop and go, that brief stop for the pressure

:05:53 20 sensing, is that found in other insufflators?

:05:55 21 A. Certainly.

:05:56 22 Q. If we could move on to the next slide, slide 10,

:05:59 23 Mr. Splansky.

:05:59 24 What is shown here, Dr. Collins?

:06:01 25 A. So this is the, what I call the air barrier mixing

Collins - direct

:06:05 1 zone. So as you can well imagine, you get those jets coming  
:06:08 2 in. There's a lot of turbulence. Mixing up the gas in that  
:06:11 3 space, so all of that gas is mixing. And the pressure at  
:06:15 4 the top, right up here, this is all open to the atmosphere.  
:06:19 5 The pressure of the air is atmosphere, and then down here,  
:06:23 6 the pressure is at the, the elevated pressure inside the  
:06:27 7 abdominal cavity.

:06:28 8 Q. All right. If we could move on to the next slide, Mr.  
:06:32 9 Splanski.

:06:32 10 These white arrows, what is represented here?

:06:37 11 A. So what that represents is that because the abdominal  
:06:41 12 cavity is insufflated, the high pressure wants to leave,  
:06:45 13 wants to go to the lower pressure areas. And so the gas  
:06:49 14 would be trying to come up, but what it does, it hits that  
:06:53 15 mixing zone, the air barrier, and that prevents the gas from  
:06:57 16 coming.

:06:58 17 Q. So the pressure inside the abdomen, if the abdomen  
:07:02 18 were down here, am I right, it would be here?

:07:05 19 A. That's correct.

:07:05 20 Q. What holds that pressure inside?

:07:07 21 A. So what hold the pressure inside is the jets creating  
:07:12 22 this air barrier. Again, the jets come in at high speed,  
:07:15 23 and as they slow down, they create a higher pressure.  
:07:18 24 Again, much like your hands are slowing down the air out the  
:07:23 25 car, that creates the higher pressure in the abdominal

Collins - direct

:07:26 1 cavity.

:07:26 2 Q. Now, this air barrier that we're looking at that is

:07:31 3 colored here, is it actually visible in the AirSeal when

:07:34 4 it's working?

:07:35 5 A. No. It's just gas, so it's invisible. You can look

:07:39 6 right through it.

:07:39 7 Q. Can tools go through the barrier?

:07:41 8 A. Absolutely, tools can be inserted, samples can be

:07:45 9 removed. Absolutely.

:07:46 10 Q. You're familiar with some of the trial testimony that

:07:48 11 was given here by Dr. Burban?

:07:50 12 A. Yes.

:07:51 13 Q. Is that right?

:07:51 14 A. Yes.

:07:52 15 Q. And one opinion he provided was that AirSeal does not

:07:56 16 create a barrier.

:07:57 17 Do you agree with that?

:07:58 18 A. No, I don't.

:07:59 19 Q. Why not?

:08:00 20 A. Because if you didn't have the barrier, you wouldn't

:08:03 21 be able to maintain the pressure inside. The pressure would

:08:05 22 just go out and all the gas would leak, and clearly, the

:08:10 23 AirSeal creates that pressure barrier that maintains that

:08:13 24 stable pneumoperitoneum.

:08:15 25 Q. Now, we've heard testimony in this case that there are

Collins - direct

:08:18 1 times when gas can escape or air can come in. Can it still  
:08:23 2 be a barrier if gas can go in and out?

:08:26 3 A. Well, certainly. You know, barriers don't have to  
:08:30 4 block everything. Walking into the court today, there are  
:08:33 5 barriers outside to prevent cars from going up on the  
:08:36 6 sidewalk, but it does not prevent people from walking,  
:08:39 7 walking through. So there are all sorts of barriers. The  
:08:41 8 most important thing is to maintain, in this case, maintain  
:08:44 9 the pressure in the abdominal cavity, which is exactly what  
:08:47 10 it does.

:08:47 11 Q. Now, what would you expect to occur if the AirSeal  
:08:50 12 System didn't create a barrier?

:08:52 13 A. Again, if it didn't create a barrier, there would be a  
:08:55 14 hole, a large hole right into the abdominal cavity, and all  
:08:59 15 the gas would escape.

:09:00 16 Q. And what is your opinion as to whether the AirSeal  
:09:02 17 System creates a seal?

:09:03 18 A. Certainly. If it holds that, the pressure in creating  
:09:08 19 a seal or barrier, and, again, without it, all the gas would  
:09:12 20 escape.

:09:14 21 Q. Mr. Splanski, if we could go to slide 12, please.

:09:16 22 And, Dr. Collins, what's shown in this slide?

:09:19 23 A. Yes. So it's a recirculation. So all of the gas  
:09:23 24 that's sitting in this mixing zone, that gas is pulled out  
:09:28 25 by the pump. So there's an inlet to the pump. That's,

Collins - direct

:09:33 1 again, bringing the gas from the mixing zone. That exact  
:09:36 2 same gas then goes through the compressor and comes back out  
:09:39 3 through the high pressure line. So that's creating this  
:09:42 4 recirculation of constantly going back and forth. It's  
:09:45 5 flowing at about 30 liters per minute. So it's hauling ten  
:09:50 6 times faster than the three liters per minute constant flow  
:09:56 7 of CO2, so a high rate of circulation.

:09:58 8 Q. Mr. Splanski, if we could go back to slide 6, please.

:10:03 9 What is shown here, Dr. Collins?

:10:04 10 A. So this is two of the, two trocars on the left, the  
:10:10 11 SurgiQuest. On the right, there's a conventional access  
:10:13 12 port or trocar by applied. And both of these are sections,  
:10:16 13 so they're cut in half so they could see inside.

:10:20 14 Q. And from your work on mechanical trocars and your  
:10:23 15 analysis of the AirSeal, does the AirSeal offer any  
:10:26 16 advantages over the trocars with the mechanical seals?

:10:30 17 A. Yes, certainly. As a system, we've heard about the  
:10:34 18 benefits of stable pneumoperitoneum and the benefits of  
:10:37 19 smoke, smoke clearance, but specifically, as you look at the  
:10:42 20 seal, in the conventional device there is, they're  
:10:48 21 elastomeric or rubberlike seals that grab onto the tools  
:10:52 22 that provide the mechanical seal.

:10:53 23 Now, the problems with that, and I spent a  
:10:55 24 lot of time in various designs trying to address these  
:10:58 25 issues, is, first, putting a sharp object, and a lot of the

Collins - direct

1 objects are sharp, they'll cut those rubber seals, and when  
2 you cut a seal, they'll create a leak.

3 Also, there's a phenomena, I call it thick  
4 slip, where because there's a rubber-grabbing tool, as you  
5 try to put that tool through the rubber, there's friction  
6 pulling it, and there's a difference between what's called  
7 static and dynamic friction. As you push it through, it can  
8 then stick and go further.

9 The last thing you want as a surgeon is to  
10 have trouble manipulating tools. And without that, just  
11 with the open area SurgiQuest, that doesn't happen anymore.  
12 Certainly, there's a big advantage. You've heard about  
13 removing tissue. You can imagine trying to pull tissue  
14 samples out back through those seals. A lot of tissue will  
15 be -- will get caught in. Inserting instruments like  
16 optical instruments, you know, that will pick up  
17 contaminants as they go through.

18 Also, we have talked about the benefits of  
19 pneumoperitoneum, and that's not only when gas leaks, but  
20 you can imagine, if you are sticking in another trocar doing  
21 something else, you're putting pressure on the abdominal  
22 cavity. If you had a complete block, what could happen is  
23 the pressure in your abdominal cavity will go up. It will  
24 go up where you want it set up, whereas here in the opening,  
25 if there's extra pressure, that gas will go out so it



Collins - direct

:12:26 1 maintains pressure even on those circumstances.

:12:28 2 Q. Now, just briefly, Dr. Collins, on the IFS box, which  
:12:32 3 is actually sitting in the corner to one side of the jury,  
:12:36 4 what's the function of the box?

:12:39 5 A. Well, the function of the box is to provide that,  
:12:41 6 CO2 and then the recirculation, takes the gasses and  
:12:45 7 recirculates the gas to maintain the pressure in the  
:12:48 8 abdominal cavity.

:12:49 9 Q. The IFS, does it provide carbon dioxide throughout the  
:12:52 10 entire procedure?

:12:53 11 A. Yes. Throughout the entire procedure minus the brief  
:12:58 12 stops of the pressure sensor.

:12:59 13 Q. If we could advance to slide 13, Mr. Splanski.  
:13:02 14 What is shown here, Dr. Collins?

:13:08 15 A. This just basically shows the entire system with the  
:13:11 16 fact that the three to eight liters per minute of gas coming  
:13:14 17 in, because the volumes stay the same, and three to  
:13:18 18 eight liters per minute of gas must leave the abdominal  
:13:21 19 cavity and basically leaves by going out through the top.

:13:24 20 Q. All right. I would like to turn briefly to the smoke  
:13:27 21 removal function of the AirSeal System when it's used in the  
:13:30 22 AirSeal mode.

:13:31 23 Is there a filter on the AirSeal System?

:13:34 24 A. Yes, there is.

:13:35 25 Q. Where is it located?

Collins - direct

:13:37 1 A. It's located in the tube set, part of the tube set  
:13:41 2 that connects to the box.

:13:43 3 Q. And if we could go to slide 14, please.

:13:47 4 Is that what's shown here, Dr. Collins?

:13:49 5 A. That is correct. So you can see the tubes here. This  
:13:53 6 is the part of the tube set that connects to the box. You  
:13:57 7 can see the -- a little hard to see here, but there's filter  
:14:01 8 material in there, and that's the other end that connects  
:14:03 9 directly to the AirSeal trocar.

:14:04 10 Q. And what is the filter that's in here? What does it  
:14:08 11 filter?

:14:09 12 A. It's a particle filter.

:14:10 13 Q. All right. So what type of things would be filtered  
:14:12 14 out by it?

:14:12 15 A. Well, small particles, smoke particles, viruses,  
:14:15 16 bacteria, those sorts of things.

:14:17 17 Q. Now, is any smoke released through the top of the  
:14:20 18 AirSeal port?

:14:21 19 A. Yes. Somewhat.

:14:23 20 Q. From your analysis, what is the concentration of smoke  
:14:26 21 that leaves the top of the port in comparison to what is  
:14:29 22 accumulated in the abdominal cavity?

:14:31 23 A. Well, really, it's kind of a two-step process. So in  
:14:36 24 that mixing zone, all the gas that's coming up will mix, and  
:14:40 25 a large fraction of that gas will go over to the filters.

Collins - direct

1 So the rate of 30 liters per minute. The rest goes out the  
2 top. So the dilution would be about 10 to 20 percent of the  
3 concentration of the smoke in the abdominal cavity will be  
4 the concentration in the, in that mixing zone, and that's  
5 what -- that's what leaves.

6 You also can remember that that smoke  
7 elimination happens constantly. So it's not like you're  
8 building up large concentrations of smoke and then releasing  
9 it. The smoke levels are always being dissipated, so the  
10 level of smoke in the abdominal cavity stays low, which they  
11 want to maintain the high visibility.

12 Q. And then when the smoke or gas comes out of the top of  
13 the port, what happens to it?

14 A. It goes into the surgical suite where it's right at  
15 the, right at the patient level, and it gets pulled into the  
16 airstreams in the operating room that typically come down,  
17 what's called a laminal flow over the surgeon, the patient,  
18 and then out through vents and through the hospital air  
19 handling system.

20 Q. Okay. I want to -- if you would take that slide down,  
21 Mr. Splanski.

22 Dr. Collins, I want to turn to the part of your  
23 assignment. You said you reviewed some of the opinions  
24 offered by Dr. Burban in this case?

25 A. I did.

Collins - direct

:16:43 1 Q. And did you review the testing he performed with the  
:16:48 2 AirSeal device?

:16:49 3 A. I did.

:16:50 4 Q. Did you do any of your own testing for this case?

:16:53 5 A. No, I didn't need to. I was looking at Dr. Burban's  
:16:56 6 tests and analyzing those.

:16:58 7 Q. Let's go through these, starting with air entrainment.  
:17:04 8 Did you review the experiments that Dr. Burban testified  
:17:07 9 about regarding air entrainment of AirSeal?

:17:10 10 A. I did.

:17:10 11 Q. What was your overall assessment on the design of  
:17:12 12 these tests?

:17:13 13 A. Well, my overall assessment was the key thing, the  
:17:16 14 tests were running for very long periods of time. They were  
:17:19 15 running for five minutes continuously, which I understand is  
:17:23 16 not typical in laparoscopic procedures.

:17:27 17 Q. Dr. Burban testified that AirSeal entrains air  
:17:30 18 directly into the abdomen. Do you agree with that?

:17:32 19 A. No, I don't.

:17:33 20 Q. Why not?

:17:34 21 A. Again, as I described, the air comes into that mixing  
:17:38 22 zone, that mixing zone mixes everything around with a large  
:17:42 23 fraction of it getting pulled over to the filter and back.  
:17:45 24 Then when air does move to the abdominal cavity it comes  
:17:50 25 from the mixing zone.

Collins - direct

:17:51 1 Q. Based on your review, are there circumstances with  
:17:56 2 AirSeal where no air enters the abdomen?

:17:58 3 A. Certainly.

:17:58 4 Q. What is that?

:17:59 5 A. A great deal of the time, when there are no excessive  
:18:02 6 leaks out of the abdominal cavity, that there was that three  
:18:06 7 liters per minute that continues to flow in and that flows  
:18:09 8 out in the purging of the air in that that would be purged  
:18:13 9 but doesn't allow any additional air into the abdominal  
:18:18 10 cavity.

:18:18 11 Q. We have seen in this case the 510(k) application to  
:18:21 12 the FDA, I think you have seen the summary put up that  
:18:26 13 classified the AirSeal as a carbon dioxide insufflator, if  
:18:30 14 you recall that?

:18:30 15 A. Yes.

:18:30 16 Q. Do you have agree with that classification?

:18:32 17 A. Yes, most definitely.

:18:34 18 Q. Why?

:18:34 19 A. Because it is using CO2 to create the peritoneum and  
:18:39 20 it's being used throughout the procedure, and it's through  
:18:43 21 the entire procedure in essence to recirculate it and  
:18:43 22 maintain the pressure.

:18:44 23 Q. In the AirSeal system, we have talked about leaks, but  
:18:47 24 what happens when the leak is repaired or closed?

:18:49 25 A. Yes. So we can look at what is repaired or closed,

Collins - direct

:18:54 1 what happens is the pressure remains stable. But at this  
:18:58 2 point more CO2 is coming in. That basically washes out any  
:19:03 3 air. Within a very short period of time, any air that was  
:19:06 4 in the abdominal cavity is out and it's back to the impure  
:19:11 5 CO2.

:19:11 6 Q. Mr. Splansky, if we could go to Slide 15, please. Dr.  
:19:22 7 Collins, if you would take us through the slide,  
:19:24 8 particularly with respect to what you were just speaking  
:19:26 9 about regarding the leak repair?

:19:28 10 A. Sure. This is a figure from Dr. Burban's report. And  
:19:33 11 it's a chart that on the x axis here, I know it's hard to  
:19:38 12 read, that's the time going forward in seconds, starting at  
:19:41 13 zero, up to 420. So it lasts about six months. On the  
:19:46 14 vertical axis here is the air concentration. Starting at  
:19:52 15 minus ten, it should be starting at zero, and going up to  
:19:56 16 about 60.

:19:57 17 The experiment, this is an air entrainment,  
:20:02 18 basically he is using 15 millimeters of pressure in the  
:20:05 19 abdominal cavity. At high smoke evac, that would be the  
:20:11 20 eight liters per minute of CO2 flowing through. And he  
:20:14 21 created a leak of 16.3 liters per minute coming out.

:20:20 22 So when he created that leak, what you can see  
:20:22 23 is in the concentration of air starting at zero and then  
:20:27 24 over the five minutes, it got up to about 50 percent of air.

:20:32 25 Q. I didn't mean to interrupt you, Dr. Collins. So

Collins - direct

:20:36 1 during this period the leak is continuously open. Is that  
:20:40 2 right?

:20:40 3 A. Correct.

:20:41 4 Q. What is shown when the leak is repaired?

:20:44 5 A. So the leak stopped. They did that at about the  
:20:48 6 five-minute mark. You can see how rapidly the air  
:20:52 7 concentration drops, it drops to ten percent at about 30 or  
:20:57 8 40 seconds, it drops to 95 percent in well under a minute.  
:21:03 9 Well under a minute you are back to very, very high  
:21:06 10 concentrations of CO2.

:21:07 11 Q. What happens to the air that was entrained?

:21:11 12 A. All of that air gets pushed out through the trocar  
:21:14 13 into the surgical suite.

:21:17 14 Q. I want to ask you one more question about this graph.  
:21:21 15 With regards to shorter leaks, the leak we looked at, I  
:21:26 16 guess you indicated it went for some amount of minutes. Is  
:21:29 17 that right, here?

:21:30 18 A. That's correct, it went for five minutes.

:21:31 19 Q. We heard some of the surgeons testify that, for  
:21:34 20 example, for suction, they were only using a second or two  
:21:37 21 at a time?

:21:37 22 A. Yes.

:21:39 23 Q. Where would that be on this graph, what would that  
:21:41 24 look like?

:21:42 25 A. In a second or two you are basically at the beginning,

Collins - direct

:21:45 1 you won't see any measurable air concentration at all.

:21:49 2 Q. If you would take that slide down, some explanation.

:21:56 3 You have reviewed -- Dr. Burban has established  
:21:58 4 that one of the things he testified to was when there was a  
:22:02 5 severe leak the AirSeal system could not recover and the air  
:22:06 6 entrainment would not be temporary as it states in the  
:22:09 7 instructions for use. Do you agree with that?

:22:11 8 A. No, not at all.

:22:12 9 Q. Why not?

:22:12 10 A. His own testing shows that is not the case. And  
:22:17 11 certainly, the experience I have heard from surgeons -- his  
:22:21 12 own testing --

:22:21 13 Q. Should I put the slide back up?

:22:23 14 A. No. The testing itself shows within a minute you are  
:22:27 15 back to a very high concentration of CO2.

:22:29 16 Q. One last source of questions on this area.

:22:35 17 We heard about a leak warning in this case. I  
:22:38 18 think you were here for Mr. Azarbarzin's testimony that the  
:22:41 19 warning would go off when the percentage of carbon dioxide  
:22:46 20 dropped below 70 percent. Is that consistent with your  
:22:49 21 review of the device?

:22:50 22 A. Yes, it is.

:22:50 23 Q. You also reviewed documentation for an earlier version  
:22:53 24 of the device in connection with the case. Correct?

:22:56 25 A. That's correct.



Collins - direct

:22:56 1 Q. And did that system have a similar leak warning?

:22:59 2 A. It had a similar leak warning plus extra features.

:23:02 3 Q. What were those extra features?

:23:07 4 A. If the leak persisted for longer periods of time that

:23:11 5 system would shut down.

:23:12 6 Q. Does the system shut down on the current system?

:23:17 7 A. No, that feature was removed.

:23:18 8 Q. And from what you have read and heard before in this

:23:18 9 case, what is your understanding of why that feature was

:23:18 10 removed?

:23:20 11 A. To contain that stable peritoneum is really critical

:23:23 12 throughout a procedure, particularly if there are conditions

:23:25 13 of high leak and you want to fix something, that is when you

:23:28 14 want your visibility. So surgeons wanted the

:23:31 15 pneumoperitoneum to remain in place.

:23:32 16 Q. Let's turn to the subject of surgical smoke. In

:23:37 17 connection with this case, did you review Dr. Burban's

:23:40 18 testing regarding surgical smoke?

:23:42 19 A. I did.

:23:42 20 Q. From your analysis what does he set out to test?

:23:45 21 A. He set out to test concentrations of different gasses

:23:48 22 at various points within the system.

:23:50 23 Q. What trocars are access --

:23:54 24 A. Just the AirSeal.

:23:55 25 Q. Did Dr. Burban test any Lexion products with regard to

Collins - direct

:23:59 1 smoke filtration?

:24:01 2 A. No.

:24:01 3 Q. Did Dr. Burban, did you see any results that compared  
:24:04 4 AirSeal to surgical smoke that would be released in open  
:24:09 5 surgery?

:24:09 6 A. No.

:24:09 7 Q. Now, we have heard some testimony about venting  
:24:13 8 trocars in the operating room. Did Dr. Burban's test  
:24:16 9 compare AirSeal to venting a conventional trocar?

:24:18 10 A. No.

:24:18 11 Q. Did you review the locations with respect to the  
:24:25 12 AirSeal system at which the smoke was measured?

:24:28 13 A. I did.

:24:28 14 Q. What is your assessment of that?

:24:30 15 A. Well, the locations, I think there are four locations,  
:24:33 16 three of them were at various points within the tube set of  
:24:37 17 the abdominal cavity. And a fourth was right at the exit of  
:24:42 18 the trocar.

:24:42 19 Q. And what is your opinion with regard to the use of  
:24:46 20 those locations for measurement?

:24:48 21 A. Well, I am not really sure what value there is. In  
:24:52 22 terms of what the values of the gasses are internally, it  
:24:57 23 doesn't really matter a whole lot. And the gas that is at  
:25:00 24 the exit, basically, that concentration is far away from  
:25:04 25 where the individuals in the surgical suite are and

Collins - direct

:25:07 1 typically it's downstream of the air that washes over the  
:25:11 2 patient. So it gets carried away to the vents.

:25:14 3 Q. So based on your understanding as an engineer, can you  
:25:17 4 draw any conclusions from Dr. Burban's smoke data?

:25:22 5 A. Not much, not really, no.

:25:23 6 Q. Let's turn to heat and humidity. Did you review Dr.  
:25:29 7 Burban's tests in this area?

:25:30 8 A. I did.

:25:31 9 Q. What did Dr. Burban test?

:25:33 10 A. He basically created a simulated abdomen and put water  
:25:37 11 into it and tested how much water was left in that.

:25:46 12 Q. What devices did Dr. Burban test?

:25:48 13 A. He used the AirSeal, he used the Synergy trocar. And  
:25:53 14 he used the PneumoSure conventional trocar.

:25:58 15 Q. Did Dr. Burban provide any testing results with  
:26:02 16 Lexion's Insuflow?

:26:03 17 A. No.

:26:03 18 Q. Did he make any comparison between heat and humidity  
:26:08 19 with regard to the Insuflow and the AirSeal?

:26:11 20 A. No.

:26:11 21 Q. With regard to the testing you said he did on Synergy,  
:26:14 22 what insufflator did he use?

:26:16 23 A. He used the iFS.

:26:18 24 Q. Now, we have heard some testimony about whether  
:26:21 25 Lexion's products could be connected to the AirSeal iFS.

Collins - direct

:26:25 1 How is that possible?

:26:27 2 A. He used it in conventional insufflation mode, where it  
:26:34 3 acts like a conventional insufflator. So he used it as a  
:26:36 4 iFS for use in a conventional trocar.

:26:38 5 Q. Is there anything special a user would have to do to  
:26:42 6 hook up the Synergy product to the AirSeal product other  
:26:46 7 than what Dr. Burban showed?

:26:49 8 A. No.

:26:49 9 Q. Now, for the AirSeal system, let's concentrate on  
:26:53 10 those tests. Did Dr. Burban do any testing on temperature  
:26:57 11 maintained by the inflation gas?

:26:59 12 A. He did not report any temperature data. He said in  
:27:02 13 his report that he had a thermocouple, which is a type of  
:27:05 14 thermometer. He did not report any temperature data.

:27:07 15 Q. Did Dr. Burban test any relative humidity?

:27:11 16 A. No, he did not test relative humidity.

:27:14 17 Q. What did he test?

:27:14 18 A. He tested how much water left the abdominal cavity or  
:27:19 19 the simulated abdominal cavity.

:27:21 20 Q. Is there a relationship between this water loss and  
:27:24 21 relative humidity?

:27:25 22 A. Not in this case. They are really independent things.

:27:28 23 Q. Why is that?

:27:30 24 A. Well, because the humidity is the amount of moisture  
:27:34 25 that's in the gas and the abdominal cavity where water is

Collins - direct

:27:38 1 only in there as liquid.

:27:40 2 You can well imagine, if you are in a wet zone  
:27:43 3 or steam room and you are sitting there with a bucket of  
:27:45 4 water and you took some of that water and poured it down the  
:27:49 5 drain, that would not change the humidity in the steam room  
:27:51 6 at all. If you open the door and let a bunch of air in and  
:27:56 7 out, that would change the humidity.

:27:58 8 In a surgical context, there is a lot of liquid  
:28:01 9 in the abdominal cavity, bodily fluids, blood, irrigation,  
:28:05 10 so there is basically, not infinite, but operationally a  
:28:11 11 large supply of liquid that can replace any liquid that has  
:28:16 12 evaporated.

:28:17 13 Q. Mr. Splansky, if you would put up Trial Exhibit JTX-7,  
:28:24 14 please, and go to the second page, if you would.

:28:28 15 Dr. Collins, is this a document that you  
:28:30 16 reviewed in connection with this case?

:28:33 17 A. Yes.

:28:33 18 Q. What is it?

:28:34 19 A. This first is a memo written by a SurgiQuest employee,  
:28:37 20 Mr. Ralph Stearns, on some testing results.

:28:40 21 Q. Did you review those testing results?

:28:42 22 A. I did.

:28:43 23 Q. Mr. Splansky, if you would go to Slide 17 of Dr.  
:28:48 24 Collins's set, please.

:28:50 25 Dr. Collins, what are you showing here?

Collins - direct

1 A. This is just an illustration to give you a sense for  
2 how the test was conducted. So there was a bladder, a  
3 simulated bladder, membrane, that was insufflated. And  
4 within that bladder, he had poured hot water and he got it  
5 hot to begin with at 100 degrees to be at about body  
6 temperature and then had the access port here operationally  
7 maintaining the pressure. Then he had a probe there to  
8 measure the gas in the abdominal cavity, the temperature and  
9 relative humidity.

10 Q. If we could go to Slide 18, please, what is shown  
11 here, Dr. Collins?

12 A. So this is just reproducing some of his results  
13 looking at, on the vertical axis here, that's the relative  
14 humidity, and then on the timeline here -- the x axis,  
15 excuse me, is timeline. The red bar here is the result of  
16 AirSeal. And you can see it started at 92, 93 percent  
17 relative humidity and stayed pretty constant through the  
18 five minutes of the test, where the conventional trocar, for  
19 the PneumoSure, started at about the same concentration and  
20 dropped down to about 60 percent in that same period.

21 Q. Now, you said the test was five minutes. Do you think  
22 five minutes was a fair assessment for temperature and  
23 humidity effects during surgery?

24 A. Certainly. This basically shows what are the  
25 thermodynamic effects that are going on, what are the

Collins - direct

:29:36 1 trends, and you can clearly see the difference in the two  
:29:39 2 trends within this period of time.

:29:42 3 Q. Now, we've heard some testimony about a SurgiQuest  
:29:46 4 statement maintains cavity temperature and relative  
:29:49 5 humidity. Does the testing you reviewed from Mr. Stearns  
:29:54 6 provide a reasonable basis for your assessment?

:29:58 7 A. Absolutely, yes.

:29:59 8 Q. Why?

:29:59 9 A. Because you can see that the AirSeal here basically  
:30:03 10 was able to maintain that high level of humidity, but  
:30:06 11 basically maintaining humidity over the test period.

:30:09 12 Q. Now, does Dr. Burban's testing on heating and humidity  
:30:13 13 change your conclusions?

:30:14 14 A. Not at all. He didn't measure any, didn't measure  
:30:17 15 humidity and he did not report the temperatures, so he gave  
:30:21 16 no new information.

:30:22 17 Q. Thank you, Dr. Collins. I will pass the witness.

:30:25 18 THE COURT: All right. Your witness, Mr. Wille.

:30:28 19 MR. WILLE: Your Honor, permission to approach  
:30:30 20 with binders?

:30:31 21 THE COURT: Sure.

:30:31 22 (Binders handed to the Court and to the  
:30:33 23 witness.)

:31:10 24 THE COURT: Mr. Wille?

:31:10 25 MR. WILLE: May it please the Court, Your Honor.

Collins - cross

:31:11 1 Thank you.

:31:11 2 CROSS-EXAMINATION

:31:12 3 BY MR. WILLE:

:31:13 4 Q. Good morning, Dr. Collins.

:31:14 5 A. Good morning.

:31:15 6 Q. Dr. Collins, you agree that nothing in the AirSeal

:31:17 7 System adds moisture to the insufflation gas; is that

:31:20 8 correct?

:31:20 9 A. That's correct.

:31:20 10 Q. All right. And the CO2 that flows in in the outer

:31:24 11 lumina of the trocar flows in cold and dry; is that correct?

:31:27 12 A. My understanding, yes.

:31:28 13 Q. And you have zero relative humidity; right?

:31:31 14 A. That's my understanding, yes.

:31:32 15 Q. And that three to eight liters, assuming there's no

:31:35 16 leaks, that three to eight liters is flowing continuously;

:31:37 17 is that correct?

:31:38 18 A. My estimate is a brief interruption of pressure

:31:43 19 sensing, yes.

:31:43 20 Q. Right. And that means, assuming there's no other

:31:45 21 leaks, three to eight liters is leaking out the top of the

:31:48 22 AirSeal trocar every minute?

:31:49 23 A. That's correct.

:31:50 24 Q. And that's enough to fill the abdomen one to two times

:31:53 25 a minute; is that right?



Collins - cross

:31:54 1 A. Thereabouts.

:31:55 2 Q. Okay. And you agree that moisture is removed from the

:31:59 3 patient during an operation performed with the AirSeal

:32:01 4 System; is that correct?

:32:02 5 A. Somewhat, yes.

:32:04 6 Q. Okay. In fact, the humidity graph that you put up

:32:07 7 here showing the humidity in the abdomen, the gas went in at

:32:11 8 zero relative humidity, so the humidity that was shown in

:32:14 9 the gas, that all came from evaporating moisture from the

:32:17 10 patient; is that right?

:32:18 11 A. I'm sorry. So do you want to talk about Mr. Stearns'

:32:22 12 testing?

:32:23 13 Q. Yes. In Mr. Stearns' test, the gas is going in cold

:32:26 14 and dry; right?

:32:27 15 A. That's right.

:32:27 16 Q. All right. And he used a simulated patient; right?

:32:30 17 This isn't a real patient?

:32:31 18 A. Correct.

:32:32 19 Q. But all the moisture and the gas comes from

:32:34 20 evaporating moisture inside a patient; right?

:32:37 21 A. Yes. There is a puddle of water at the base of the

:32:41 22 abdomen, and on the surface, the water would evaporate, yes.

:32:46 23 That's where the humidity came from.

:32:47 24 Q. All right. So now you indicated that the humidity

:32:50 25 stayed relatively constant throughout the test; right?

Collins - cross

:32:53 1 A. That's correct.

:32:54 2 Q. Let's keep the graph up there, please, Mr. Barnes.

:32:57 3 But, in fact, sir, there were only three data  
:32:59 4 points; right? One at the start, one at one minute, and one  
:33:02 5 at five minutes; is that right?

:33:03 6 A. That's correct.

:33:03 7 Q. Okay. So there's only three data points to look at.  
:33:07 8 We don't have a data point for the second minute, the third  
:33:10 9 minute and the fourth minute; right?

:33:11 10 A. Well, I understand you don't need a lot of data  
:33:15 11 points. You can basically look at the last point, if you  
:33:19 12 will, say five minutes. There is very little change. It's  
:33:24 13 pretty easy.

:33:24 14 Q. Okay. Now, relative humidity is a measurement of the  
:33:31 15 percentage of moisture that's in the atmosphere compared to  
:33:36 16 the maximum percentage that the air could hold at that  
:33:39 17 temperature; right?

:33:40 18 A. That's correct.

:33:40 19 Q. And so relative humidity depends upon temperature;  
:33:43 20 right?

:33:43 21 A. That's correct.

:33:44 22 Q. And so as an engineer, if I told you the relative  
:33:47 23 humidity is 60 percent and I asked you, am I going to feel,  
:33:54 24 is the air going to feel stuffy or is the air going to feel  
:33:57 25 dry, you would want to know what temperature it was at,

Collins - cross

:34:00 1 wouldn't you?

:34:01 2 A. Well, not necessarily.

:34:04 3 Q. Well, you can't tell how much moisture is in the air  
:34:08 4 just by considering relative humidity; is that correct? You  
:34:11 5 have to consider the temperature; right?

:34:14 6 A. Absolutely, but that is a different question than you  
:34:17 7 asked.

:34:17 8 Q. Okay. You graphed here -- this isn't in Mr. Stearns'  
:34:21 9 report; right? This graft?

:34:23 10 A. The data is.

:34:24 11 Q. The data is, but you created the graft; right?

:34:26 12 A. I did.

:34:27 13 Q. All right. And isn't it true that the temperature  
:34:29 14 changed during this experiment, sir?

:34:30 15 A. Yes, it is.

:34:31 16 Q. Okay. So the relative humidity that you graft here  
:34:34 17 doesn't take into account the fact that the temperature  
:34:36 18 changed, does it?

:34:37 19 A. Yes, it does. It's reporting the relative humidity.

:34:45 20 Q. But the relative humidity, if I tell you the relative  
:34:48 21 humidity is 60 percent, you can't tell me how much moisture  
:34:50 22 is in the gas, can you, sir?

:34:52 23 A. I can't, just with that piece of information, no.

:34:54 24 Q. Right. You need to know the temperature; right?

:34:57 25 A. Pressure and other things, certainly.

Collins - cross

:34:59 1 Q. Okay. So all of these data points don't make any  
:35:01 2 sense unless you consider the temperature change; isn't that  
:35:04 3 true?

:35:04 4 A. Absolutely not. It makes perfect sense. I want to  
:35:07 5 know what the relative humidity is, and you can measure the  
:35:10 6 relative humidity, and I just plotted the results of  
:35:15 7 Mr. Stearns.

:35:16 8 Q. All right. Now, you agreed with me a few minutes ago  
:35:20 9 that the gas entered the abdomen at near zero relative  
:35:25 10 humidity; is that right?

:35:26 11 A. Yes, that's my understanding.

:35:27 12 Q. All right. And so to get to the humidity that  
:35:29 13 Mr. Stearns measured, it picked up moisture from inside the  
:35:32 14 abdominal cavity; right?

:35:34 15 A. Inside the simulated abdominal cavity, yes.

:35:37 16 Q. Right. And you agreed that more moisture evaporated  
:35:40 17 from the patient in five minutes with the AirSeal than with  
:35:43 18 the conventional insufflator; is that correct?

:35:46 19 A. I don't remember looking at that.

:35:51 20 Q. Okay. Well, if we started at zero humidity and we got  
:36:06 21 up to some level of relative humidity that was higher with  
:36:09 22 AirSeal than with the conventional insufflator, it would  
:36:13 23 have to evaporate more moisture, wouldn't it, sir?

:36:16 24 A. I guess I didn't understand your question. Frankly, I  
:36:21 25 don't know how much moisture was evaporated. What I do know

Collins - cross

:36:24 1 is what was the relative humidity in the abdominal cavity  
:36:28 2 based on what Mr. Stearns measured.

:36:30 3 Q. Sir, isn't it true that the results of the experiments  
:36:32 4 mean that more moisture evaporated from the patient at five  
:36:35 5 minutes with the AirSeal than they did with a conventional  
:36:38 6 insufflator?

:36:39 7 A. Not necessarily, no.

:36:41 8 MR. WILLE: Your Honor, I would like to read  
:36:46 9 Page 381, line 23, through page --

:36:53 10 THE COURT: You have a binder there and one of  
:36:55 11 the tabs says deposition.

:36:56 12 THE WITNESS: Thank you.

:36:59 13 THE COURT: Mr. Wille is going to tell you what  
:37:01 14 he wants to read to yourself.

:37:03 15 THE WITNESS: All right. I'm sorry. What page?

:37:06 16 MR. WILLE: Page 382, line 6.

:37:14 17 MR. RYAN: I'm sorry, Your Honor.

:37:16 18 MR. WILLE: 381, line 23, through 382, line 6.

:37:25 19 BY MR. WILLE:

:37:25 20 Q. Have you found that page, Mr. Collins?

:37:27 21 A. I did.

:37:28 22 Q. Okay. Have you reviewed the testimony?

:37:29 23 A. I'm sorry. So starting at line --

:37:32 24 Q. 381, line 23.

:37:34 25 A. Through 382, line 6.

Collins - cross

:37:48 1 (Pause while witness reviewed deposition  
:37:51 2 transcript.)

:37:52 3 BY MR. WILLE:

:37:52 4 Q. Have you had a chance to review the testimony?

:37:54 5 A. I read that, yes.

:37:55 6 Q. So were you asked the following question and did you  
:37:57 7 give the following answer:

:37:59 8 "All right. And that means more moisture  
:38:01 9 evaporated from the patient in five minutes with the AirSeal  
:38:03 10 than did with the conventional insufflator; correct?

:38:07 11 "Answer: Yeah, there was more moisture in the  
:38:08 12 air, in the cavity with the IFS."

:38:11 13 Were you asked that question and did you give  
:38:14 14 that answer?

:38:14 15 A. I did, and the context of my answer in this particular  
:38:17 16 case was I was looking at how much moisture is in the  
:38:20 17 abdominal cavity, in that space in the abdominal cavity, and  
:38:24 18 because I know that the relative humidity was higher, I know  
:38:27 19 there was more moisture in the space, and the only place  
:38:32 20 that moisture can come from was the liquid.

:38:35 21 Q. Okay. And the only place that moisture could come  
:38:38 22 from was the liquid means that moisture came from the  
:38:41 23 simulated patient; right?

:38:42 24 A. It came from the liquid, the pool of water.

:38:44 25 Q. Okay. And you further agree that evaporation pools

Collins - cross

:38:47 1 the patient; is that correct?

:38:48 2 A. Yes. When it is evaporated, it takes energy. That's  
:38:55 3 correct.

:38:55 4 Q. Okay. Let's talk about surgical smoke, and hopefully,  
:38:59 5 we can keep this short here.

:39:01 6 You agree that Dr. Burban's tests demonstrate  
:39:04 7 that the AirSeal does not filter gasses; is that right?

:39:06 8 A. Well, his data was pretty noisy, but I saw no evidence  
:39:13 9 that the AirSeal filtered gasses, which is consistent with  
:39:16 10 my understanding of the particle filter.

:39:17 11 Q. Right. You didn't need to be an expert in filtration  
:39:20 12 to know that the ULPA filter is a particle filter?

:39:25 13 A. That's correct.

:39:26 14 Q. You're not an expert in filtration?

:39:28 15 A. I'm not.

:39:29 16 Q. You knew that filter couldn't filter toxic  
:39:33 17 carcinogenic gasses?

:39:35 18 A. It doesn't filter gasses. It's a particle filter.

:39:37 19 Q. Right. You also agree if the AirSeal System alone is  
:39:39 20 being used for smoke evacuation, there's no place for those  
:39:43 21 toxic and carcinogenic gasses to go other than into the  
:39:47 22 operating room or being absorbed by the patient; is that  
:39:50 23 correct?

:39:50 24 A. There could be suction. I guess you said if it's just  
:39:56 25 being used alone?

Collins - cross

:39:57 1 Q. Yes.

:39:57 2 A. Yes, that's where we're going.

:39:59 3 Q. Okay. Let's talk about air entrainment. You do agree  
:40:08 4 that in the case where there's a large leak and air is being  
:40:12 5 sucked into the abdomen, that some of the air is being  
:40:16 6 sucked into the abdomen without being filtered; is that  
:40:19 7 correct?

:40:19 8 A. Well, again, all of the air goes into the mixing zone  
:40:24 9 where it's mixed. A large fraction of it goes through the  
:40:27 10 filter, but some of it doesn't go through the filter. Some  
:40:30 11 of it will go into the abdomen through a mixing zone  
:40:34 12 directly.

:40:34 13 Q. Okay. Now, I also think you testified on direct that  
:40:38 14 you thought John Burban's tests of five minutes were too  
:40:41 15 long; is that right?

:40:42 16 A. I thought they were not representative of surgery.  
:40:45 17 That's correct.

:40:45 18 Q. Okay. So we had Dr. Dulemba, a very accomplished  
:40:52 19 gynecologic surgeon that gets patients from all over the  
:40:56 20 world --

:40:57 21 MS. PASCAL: I'm going to object.

:40:58 22 THE COURT: Mr. Wille, you don't get to testify.  
:41:00 23 Let me leave it there. Okay?

:41:01 24 MR. WILLE: Okay.

:41:01 25 THE COURT: Please refrain from those kinds of



Collins - cross

:41:04 1 comments.

:41:04 2 MR. WILLE: Okay.

:41:05 3 BY MR. WILLE:

:41:05 4 Q. Sir, did you review Dr. Dulemba's testimony?

:41:08 5 A. I don't recall reviewing it, no.

:41:09 6 Q. On hysterectomy?

:41:10 7 A. I don't recall it.

:41:11 8 Q. Okay. Well, did you review Dr. Ramirez's testimony?

:41:14 9 Were you here for Dr. Ramirez?

:41:16 10 A. I was here for Dr. Ramirez, yes.

:41:18 11 Q. Okay. And he told you that -- didn't he testify that

:41:21 12 when the uterus is removed, that you can have a leak for

:41:25 13 five minutes up to a greater number of minutes?

:41:28 14 A. I don't remember what his exact testimony was.

:41:32 15 Q. Okay. Well, you do know that the shutdown feature was

:41:36 16 removed from the AirSeal System; is that right?

:41:39 17 A. That's correct.

:41:40 18 Q. Because doctors were complaining that the unit was

:41:44 19 shutting off; right?

:41:45 20 A. I don't know that they were complaining about it.

:41:47 21 Q. Okay. Well, sir, it was about five minutes, a

:41:53 22 five-minute leak before you would have that shut down occur,

:41:55 23 wasn't it?

:41:55 24 A. My recollection, yes.

:41:57 25 Q. Okay. So if leaks couldn't last for five minutes,

Collins - cross

:42:00 1 there would be no need to remove that feature from the  
:42:03 2 device; isn't that true?

:42:05 3 A. You want features to protect in its worst case  
:42:13 4 scenario. Just because the worst case never happens doesn't  
:42:16 5 mean you don't want features protecting the worst case  
:42:19 6 scenario.

:42:20 7 Q. Sir, you're aware there's still a leak alarm that  
:42:22 8 occurs; right?

:42:23 9 A. Yes.

:42:24 10 Q. Okay. You agree when that leak alarm goes off, we're  
:42:27 11 no longer talking about a short or modest leak at that  
:42:30 12 point?

:42:30 13 A. The leak has persisted for at least two minutes.

:42:33 14 Q. Now, you did not do any testing of your own; is that  
:42:44 15 right?

:42:44 16 A. No, did not.

:42:45 17 Q. Did SurgiQuest tell you that you couldn't do any  
:42:48 18 testing on your own?

:42:49 19 A. No, they did not.

:42:50 20 Q. So you could have done your own tests?

:42:51 21 A. If I felt I needed to, I would have.

:42:53 22 Q. Okay. And one of the things that you are testifying  
:42:56 23 about is how much air gets into the abdomen during a leak;  
:43:00 24 is that right?

:43:00 25 A. I think I'm testifying about the results I've seen of

Collins - cross

:43:03 1 those tests.

:43:04 2 Q. Okay. And are you aware of any testing that shows  
:43:11 3 what the maximum percentage of air that can get into the  
:43:13 4 abdomen is when you use the AirSeal System?

:43:15 5 A. I've not seen that, no.

:43:24 6 MR. WILLE: Mr. Barnes, can I have Exhibit, or  
:43:27 7 slide 2, please.

:43:33 8 BY MR. WILLE:

:43:36 9 Q. Lexion Exhibit 324 is a patent that you're listed as  
:43:40 10 an inventor on; is that right?

:43:42 11 A. Yes.

:43:43 12 Q. Okay. And it's a patent for a universal seal for a  
:43:46 13 trocar assembly; right?

:43:48 14 A. That's correct.

:43:48 15 Q. All right. And I think you indicated that most  
:43:51 16 conventional trocars have a seal; right?

:43:53 17 A. That's correct.

:43:54 18 Q. All right. And they've been called seals for years;  
:43:56 19 right?

:43:57 20 A. I assume so.

:43:59 21 Q. This patent is from 1994. It refers to it as a seal;  
:44:02 22 right?

:44:03 23 A. Yes, it does.

:44:04 24 Q. All right. And you indicate in your patent, as is  
:44:06 25 well-known in the art, seal member assembly 28 cooperates

Collins - cross

:44:10 1 with obturator 14 or an implement extending through trocar  
:44:15 2 tube 12 to sealingly engage the outer surface thereof  
:44:19 3 and thereby preclude the passage of fluids through handle  
:44:23 4 16.

:44:24 5 Did I read that correctly?

:44:26 6 A. Yes, you did.

:44:26 7 Q. What that means is the rubber seal seals around the  
:44:29 8 instrument and precludes the passage of gas; is that  
:44:31 9 correct?

:44:32 10 A. That's correct.

:44:32 11 Q. Right. Now, you indicated if a seal gets cut, that it  
:44:38 12 can leak; is that right?

:44:39 13 A. That's one -- yes, it can.

:44:41 14 Q. And if it's leaking, it's not acting as a seal  
:44:44 15 anymore; isn't that right?

:44:45 16 A. A leaking seal.

:44:46 17 Q. Okay. Now, on direct you testified about what an air  
:44:52 18 barrier was.

:44:53 19 Do you recall that?

:44:53 20 A. I do.

:44:54 21 Q. All right. And in your expert report, you used the  
:44:58 22 dictionary definition from the Miriam-Webster Online  
:45:02 23 Dictionary about what an air barrier was?

:45:05 24 A. I did reference that, yes.

:45:07 25 Q. Okay. When you did your report, did you use that same

Collins - cross

:45:09 1 dictionary to look up the definition of AirSeal?

:45:12 2 A. I did not, no.

:45:13 3 Q. Were you aware that that dictionary defines AirSeal as  
:45:17 4 a seal to prevent passage of air or vapor?

:45:20 5 A. I didn't see it. I don't know.

:45:24 6 Q. Is that a reasonable definition of an AirSeal to use,  
:45:27 7 sir?

:45:28 8 A. Prevent -- it's generally consistent. That doesn't  
:45:33 9 mean that it prevents all gas or air or vapor or whatever  
:45:37 10 the definition was.

:45:38 11 MR. WILLE: No further questions, Your Honor.

:45:39 12 THE COURT: All right. Redirect?

:45:41 13 MS. PASCAL: No questions, Your Honor.

:45:42 14 THE COURT: Thank your Honor Dr. Collins. Be  
:45:45 15 careful stepping down. With the witness thank you.

:45:46 16 (Witness excused.)

:45:48 17 THE COURT: Let's take our morning break.

:45:58 18 MR. RYAN: Thank you, Your Honor.

:45:59 19 (The jury was excused for a short recess.)

:46:03 20 (Short recess taken.)

:05:27 21 MR. RYAN: Your Honor, Mr. Wille's case rested.  
:05:30 22 He rested after Dr. Collins's testimony.

:05:32 23 THE COURT: Do you want to rest in front of the  
:05:34 24 jury?

:05:34 25 MR. WILLE: No, Your Honor. Not necessary,

1 unless the Court would like.

2 THE COURT: No.

3 MR. WILLE: We rest.

4 THE COURT: Maybe I should ask. Or I can tell  
5 them.

6 MR. WILLE: Your Honor, because we took the  
7 witnesses in their case.

8 THE COURT: Yes, I agree.

9 MR. RYAN: We wanted to let the Court know that  
10 the case had rested. We would like of course as a result of  
11 him resting permission to submit our Rule 50 motion.

12 THE COURT: You go ahead and do that.

13 MR. RYAN: When would you like that?

14 THE COURT: Whenever you want. I am going to  
15 reserve on it but not deny. But I will reserve for the  
16 record.

17 MR. RYAN: Is tomorrow morning okay?

18 THE COURT: Sure.

19 MR. RYAN: Yes.

20 MR. WILLE: Thank you, Your Honor.

21 (Jury enters courtroom at 11:05 a.m.)

22 THE COURT: Please take your seats, ladies and  
23 gentlemen.

24 MS. KRAFT: Your Honor, SurgiQuest would like to  
25 call Dr. Douglas Ott, chief medical officer of Lexion, by

Ott - depo.

:06:51 1 deposition.

:06:52 2 THE COURT: Okay.

:06:52 3 (Deposition of Douglas Ott played as follows.)

:06:59 4 "Question: Good morning, Dr. Ott.

:07:00 5 "Answer: Good morning.

:07:00 6 "Question: Are you still performing surgeries  
:07:02 7 today?

:07:03 8 "Answer: No.

:07:03 9 "Question: When was the last time you performed  
:07:05 10 a surgery on a human being?

:07:07 11 "Answer: Best of my recollection, it would have  
:07:13 12 been some -- between 2002 and 2003.

:07:17 13 "Question: Are you involved at all in the  
:07:19 14 training of the sales force?

:07:21 15 "Answer: On the medical side, yes.

:07:23 16 "Question: Dr. Ott, before the break I handed  
:07:26 17 you -- or the court reporter handed you Exhibits 99 through  
:07:32 18 102, which I'll represent to you I printed off Lexion's  
:07:36 19 website in January of this year under the scientific studies  
:07:39 20 section.

:07:39 21 "Are you aware that Lexion posts certain -- or  
:07:43 22 lists certain scientific or -- studies or publications on  
:07:49 23 its website?

:07:53 24 "Answer: I'm aware that they do, yes.

:07:56 25 "Question: Okay. Are you aware of articles

Ott - depo.

:07:59 1 that have been tested on warm and humidified insufflation  
:08:02 2 gas and have not seen the same results as papers presented  
:08:08 3 on the websites?

:08:11 4 "Answer: I have seen some of those articles.

:08:13 5 "Question: So by the mid-2000s, 2005, you'd  
:08:20 6 been publishing, and, I presume, speaking about warm and  
:08:24 7 humidified gas for some time, correct?

:08:27 8 "Answer: Yes, ma'am.

:08:27 9 "Question: What would you say the percentage of  
:08:29 10 surgeons in the U.S. in 2005 is that were using warm and  
:08:33 11 humidified carbon dioxide gas?

:08:36 12 "Answer: Oh, it would be -- it would be a total  
:08:40 13 guess. I'm not aware of where there's anything posted, say,  
:08:44 14 three years later of how many laparoscopies were done in a  
:08:48 15 certain year, like what's the population of New York,  
:08:51 16 whatever.

:08:51 17 "Question: Okay. And the time you mentioned  
:08:55 18 was 2005?

:08:57 19 "Answer: 2005. My guess, which is totally a  
:09:00 20 guess, is that the amount of surgeries that involved warm  
:09:07 21 wet was 1 to 2 percent.

:09:14 22 "Question: Well, let's start at the present.  
:09:16 23 Are you aware that there is debate in the scientific  
:09:19 24 literature as to the clinical benefits of warm, humidified  
:09:25 25 insufflation gas?



Ott - depo.

:09:26 1 "Answer: Well, I think people can debate  
:09:28 2 anything, even at extremes. The thing is, is that -- you  
:09:33 3 know, the -- what will prevail is actually what happens.  
:09:37 4 So, you know, dealing with the -- at this time, they may not  
:09:41 5 have had enough papers to come up any other conclusion than  
:09:47 6 what they did.

:09:49 7 "I'm aware of two meta-analyses that came up  
:09:53 8 with two separate conclusions that validated the use of  
:09:56 9 human humidification.

:09:58 10 Q. Okay. Let's try to break this down. So you're aware  
:10:02 11 or -- that there is this section in the SurgiQuest AirSeal  
:10:09 12 iFU that warns of the possibility of air entrainment,  
:10:14 13 correct?

:10:15 14 "Answer: That's correct.

:10:16 15 "Question: Would you agree with me that if a  
:10:18 16 surgeon opened up the instructions for use they would find  
:10:22 17 this warning of the possibility of air entrainment in the  
:10:25 18 SurgiQuest iFUs?

:10:26 19 "Answer: So the question is would they find  
:10:28 20 this in the instructions for use. If they read it  
:10:31 21 completely and read everything, they would -- and that is  
:10:34 22 there, they would have seen it.

:10:36 23 "Question: This Exhibit 109, at least at the  
:10:39 24 top header, appears to be an e-mail from your nonLexion  
:10:43 25 Medical e-mail address to your Lexion Medical e-mail

Ott - depo.

1 address, dated January 13, 2014. Subject line, Forward 'FDA  
2 letter and exhibits about SurgiQuest devices.'

3 "Underneath it is an e-mail from a Bud Horwath  
4 to yourself. Who is Bud Horwath?

5 "Answer: He's a person that Lexion uses as an  
6 FDA consultant. He's knowledgeable in things you do with  
7 the FDA. And he's a consultant.

8 "Question: Now, in this e-mail, it might be  
9 easier to kind of look down, because it seems to be a chain  
10 of e-mails. But he's suggesting that you should author some  
11 type of letter, at least in his -- the e -- the e-mail that  
12 appears just below your e-mail header. Do you know what  
13 letter he's speaking of?

14 "Answer: It would have been the letter that I  
15 eventually sent to the FDA personally as my opinion to them  
16 about the circumstance with the SurgiQuest group.

17 "Question: Did you ever hear anything else from  
18 the FDA?

19 "Answer: No.

20 "Question: Okay. Never received any  
21 correspondence back from them on the correspondence you had  
22 sent?

23 "Answer: No, no. No mail, no e-mail, no phone  
24 calls.

25 "Question: Did you do any followup after that?

Ott - depo.

:12:26 1 "Answer: No.

:12:27 2 "Question: Okay. You can set that aside. Have  
:12:35 3 you ever distributed this graph or a graph on complication  
:12:39 4 rates for the SurgiQuest AirSeal outside of Lexion?

:12:43 5 "Answer: Yes.

:12:43 6 "Question: And who did you distribute it to?

:12:46 7 "Answer: To a number of physicians who are  
:12:49 8 colleagues who educated other people or persons who do a lot  
:12:54 9 of laparoscopy.

:12:58 10 "Question: Okay. And why did you do that?

:13:01 11 "Answer: As a colleague, they send me  
:13:03 12 information about things that they think I might not be  
:13:06 13 aware of, and so it's not an uncommon occurrence for a  
:13:13 14 professional colleague to send another professional  
:13:16 15 colleague information about something that they think  
:13:22 16 someone else might not know about or they might be  
:13:27 17 interested in.

:13:28 18 "Question: Do -- is it your view that  
:13:30 19 SurgiQuest is a competitor of Lexion?

:13:32 20 "Answer: Yes.

:13:33 21 "Question: Okay. Dr. Ott, Exhibit 136 is a  
:13:36 22 collection of e-mails from you, from your personal e-mail to  
:13:43 23 various recipients, and these appear, within this  
:13:53 24 collection, to bear dates in March of 2014, and please feel  
:13:58 25 free to look through at the pages.

Ott - depo.

:14:03 1 "Okay. And each of these e-mails, generally one  
:14:07 2 individual, a copy of each e-mail is an e-mail to a single  
:14:14 3 individual, attaching or pasting in the SurgiQuest  
:14:22 4 complication rate chart; is that right?

:14:24 5 "Answer: Yes.

:14:24 6 "Question: And you sent all of these, to the  
:14:30 7 best of your knowledge?

:14:35 8 "Answer: Yes. Yes, ma'am.

:14:36 9 "Question: Dr. Ott, you were asked various  
:14:41 10 questions about heat and humidified gas. Do you recall  
:14:44 11 that?

:14:44 12 "Answer: Yes.

:14:44 13 "Question: One of the topics you were asked  
:14:47 14 about was the standard of care. Do you recall that  
:14:50 15 discussion?

:14:53 16 "Answer: Yes. Yes.

:14:55 17 "Question: What is your belief as to whether  
:14:58 18 heated and humidified gas should be the standard of care for  
:15:02 19 laparoscopic surgery?

:15:04 20 "Answer: It should be. Every person on the  
:15:07 21 face of the planet should have a -- a normal physiologic  
:15:14 22 homeostatic environment for the surgery performed in their  
:15:16 23 abdomen, and putting cold dry gas or cold dry gas into the  
:15:20 24 abdomen is not normal, and they would be at a higher risk  
:15:26 25 for either complications or untoward side effects as a

Ott - depo.

1 result of the surgery.

2 "Question: Okay. So why is it your belief that  
3 heated and humidified gas should be the standard of care?

4 "Answer: Because of the papers that have been  
5 verifying what I've been saying for years that are people  
6 that I had no influence over and that have been determined  
7 to be having beneficial clinical effects on the patient's  
8 outcome.

9 "Question: And what is -- what is your belief  
10 as to the benefits on patient outcome from using the  
11 Insuflow device?

12 "Answer: Well, one is it prevents desiccation  
13 to the tissue, the -- another is that it's been shown in the  
14 papers that there's a decrease in the amount of pain  
15 medication that's used and a decrease in the shoulder  
16 discomfort. For some reason the shoulder seems to be the  
17 area that a lot of people complain of after laparoscopic  
18 procedures, and there's a decrease in the occurrence rate of  
19 that. And that there's a -- either a quick recovery or a  
20 shorter time in the recovery room from the time of surgery  
21 until the time that they're moved to another place in the  
22 hospital or go home.

23 "Question: Okay. You mentioned patents. Did  
24 you get a patent on your method of heating and humidifying  
25 gas?

Ott - depo.

:16:58 1 "Answer: Yes.

:16:59 2 "Question: Okay. And counsel asked you some  
:17:01 3 questions about suggesting to the Food & Drug Administration  
:17:04 4 that this be the standard of care. Do you recall that?

:17:07 5 "Answer: Yes.

:17:07 6 "Question: Can the Food & Drug Administration  
:17:09 7 make something the standard of care?

:17:11 8 "Answer: No.

:17:11 9 "Question: All right. And in the 16 years of  
:17:15 10 selling the Insuf flow device, what has been your experience  
:17:18 11 as to whether the Insuf flow results in lesser postoperative  
:17:23 12 pain?

:17:24 13 "Answer: It -- the reports show that it does,  
:17:26 14 and there is patient testimonials that admit to that.

:17:33 15 "Question: All right. And in your experience  
:17:35 16 in the 16 years using the Insuf flow, what is your belief as  
:17:39 17 to whether the Insuf flow achieves a lower risk of  
:17:43 18 postoperative hypothermia?

:17:45 19 "Answer: It does.

:17:45 20 "Question: Okay. And what is your belief as to  
:17:48 21 the what -- whether the Insuf flow achieves lower analgesic  
:17:53 22 requirements?

:17:54 23 "Answer: It does. It's reported.

:17:56 24 "Question: Did -- and counsel showed you a  
:17:59 25 number of e-mails where you sent your graph to people, other

Ott - depo.

:18:03 1 surgeons that you knew around the country. Is that right?

:18:06 2 "Answer: Yes.

:18:07 3 "Question: Did any of those surgeons contact  
:18:09 4 you and tell you there was something wrong with your data?

:18:14 5 "Answer: No.

:18:14 6 "Question: Okay. After you published your  
:18:18 7 article that we discussed earlier that includes data about  
:18:22 8 complication rates of the AirSeal system, did anyone write a  
:18:27 9 letter to the editor of the journal about your article?

:18:31 10 "Answer: Not that I know of, no."

:17:58 11 MS. KRAFT: Your Honor, SurgiQuest calls Dr.  
:18:01 12 Carol Scott to the witness stand.

:18:27 13 ... CAROL A. SCOTT, having been duly  
:18:50 14 sworn as a witness, was examined and testified  
:18:52 15 as follows ...

:19:02 16 THE COURT: Pass out those binders.

:19:04 17 Good morning, Doctor.

:19:05 18 THE WITNESS: Good morning.

:19:07 19 MR. RYAN: Thank you.

:19:07 20 (Binders handed to the Court and to the  
:19:09 21 witness.)

:19:35 22 THE COURT: Counsel?

:19:36 23 MS. KRAFT: Good morning, Your Honor.

:19:38 24 May it please the Court, members of the jury, my  
:19:40 25 name is Denise Kraft. I represent SurgiQuest. With me

Scott - direct

:19:44 1 today is doctor Carol Scott on the stand.

:19:47 2 DIRECT EXAMINATION

:19:48 3 BY MS. KRAFT:

:19:49 4 Q. Good morning, Dr. Scott.

:19:49 5 A. Good morning.

:19:50 6 Q. Have you prepared a PowerPoint to assist you with your  
:19:52 7 testimony today?

:19:53 8 A. I have.

:19:54 9 Q. Okay.

:19:57 10 MS. KRAFT: Bring up the first slide,  
:20:00 11 Mr. Splansky.

:20:01 12 BY MS. KRAFT:

:20:02 13 Q. Can you please tell the jury a bit about your  
:20:03 14 background, starting with your education?

:20:05 15 A. Sure. I have a Bachelor of Science from the  
:20:09 16 University of Texas at Austin. Then I have a Master of  
:20:13 17 Science in management and a Ph.D. in marketing from  
:20:15 18 Northwestern University.

:20:17 19 I have been a professor for over 40 years. I  
:20:21 20 taught at Ohio State for three years and then I went to UCLA  
:20:25 21 in 1977, where I was a full-time regular faculty member  
:20:29 22 until 2011, when I retired from full-time teaching.

:20:33 23 Since that time I have been what is called an  
:20:36 24 emeritus. It just means you're retired. And I've been  
:20:40 25 recalled, meaning that I have been reappointed to teach



Scott - direct

1 classes, and, in particular, I spend most of my time there  
2 now in executive education as I also taught on a visiting  
3 basis at Harvard Business School and Stanford.

4 As part of my work in the executive education  
5 realm, I was a faculty member for about 25-plus years, I'm  
6 not sure exactly how many, in our UCLA medical marketing  
7 program. It's a week-long program for executive, managers  
8 and executives from companies that sell medical devices,  
9 medical diagnostics and pharmaceuticals. And they come to  
10 UCLA to work with us to improve their marketing practices  
11 and get better educated about that.

12 I'm also the faculty director for a couple of  
13 other executive programs.

14 Q. Thank you, Dr. Scott.

15 Have you performed any consumer studies?

16 A. Yes. I've done several consumer studies for academic  
17 research, and I've done probably over a hundred in  
18 connection with various cases such as this one, various  
19 types of litigation over a 30-year career of doing some of  
20 this kind of research.

21 Q. Have you performed any consumer surveys?

22 A. Yes. Most of my research is published in doing that  
23 location work. Most of it is surveys. Not all, but most of  
24 it are surveys.

25 Q. How many years have you been conducting consumer

Scott - direct

:22:10 1 research and surveys?

:22:11 2 A. I started my graduate degree in 1971, which sounds  
:22:18 3 like a long time ago, and it was, and I've been doing  
:22:22 4 consumer research ever since. So that's about  
:22:24 5 40-something-plus years.

:22:25 6 Q. You mentioned litigation earlier. Have you ever  
:22:27 7 qualified as an expert before in other courts besides the  
:22:31 8 one where you're at today?

:22:34 9 A. Yes. Definitely. Many times.

:22:36 10 Q. All right. And have you published any academic  
:22:39 11 journals?

:22:41 12 A. Published articles in academic journals, yes.

:22:44 13 Q. Okay. What is a peer reviewer?

:22:46 14 A. When someone submits an article to a journal that they  
:22:50 15 want to have published, the editor needs to evaluate that  
:22:53 16 publication, that article, to see if it's high quality, if  
:22:56 17 it's worth publishing, and the editor will send it out to  
:22:59 18 two or three people in the area, specifically in that area  
:23:02 19 that are known as experts in that area, to read it and  
:23:06 20 evaluate it and get their recommendations, and that's called  
:23:09 21 a peer, meaning a peer professional reviewing your papers to  
:23:12 22 determine its quality.

:23:14 23 Q. Have you been a peer reviewer?

:23:16 24 A. Yes, I have. I've was a member of the editorial board  
:23:19 25 for three of our journals, Journal of Marketing, Journal of

Scott - direct

1 Marketing Research, and Journal of Consumer Research, and I  
2 still am an occasional reviewer. I get asked to review  
3 papers once in a while for the journal of behavioral  
4 decision-making.

5 Q. Thank you.

6 MS. KRAFT: Your Honor, I offer Dr. Carol Scott  
7 as an expert witness in the fields of consumer research and  
8 consumer surveys.

9 THE COURT: Any objection?

10 MR. REILLY: No objection, Your Honor.

11 THE COURT: The doctor is accepted as an expert  
12 witness.

13 MS. KRAFT: Thank you.

14 BY MS. KRAFT:

15 Q. Now, Dr. Scott, were you asked to investigate an issue  
16 in conjunction with this litigation?

17 A. Yes, I was.

18 Q. And what issue were you asked to investigate?

19 A. Well, the general issue is, are complication rates  
20 involving use of the AirSeal product. Are they material to  
21 potential users, and potential users are obviously surgeons.  
22 And that means, basically, are complication rates important  
23 to surgeons.

24 Q. Okay. Thank you.

25 Slide number 4, Mr. Splanski.

Scott - direct

:24:24 1 Okay. Were you asked to design a survey to  
:24:30 2 assist with your investigation?

:24:31 3 A. Yes. A specific question that I was asked to address  
:24:35 4 within the general realm of complication rate was, I was  
:24:39 5 asked to investigate the potential effect of the chart,  
:24:44 6 which you can kind of see. It's a little blurry over there,  
:24:47 7 but I understand you've seen this chart before.

:24:49 8 This was a chart that, as just heard Dr.  
:24:55 9 Ott say, he sent out to some of his colleagues, and it was  
:24:58 10 sent by Dr. Ott, who works for Lexion. And it shows for  
:25:06 11 three different types of complications, AirSeal has a higher  
:25:09 12 rate of complication when you're using it than what this  
:25:13 13 chart calls conventional trocars.

:25:15 14 So my job was to determine whether this chart  
:25:21 15 would have any impact on the recipient's decision to  
:25:27 16 consider the AirSeal, whether it would affect their  
:25:29 17 evaluations of the AirSeal, and whether it would affect  
:25:33 18 their likelihood of trying the product. So that's a  
:25:36 19 specific issue that we're involved in.

:25:39 20 Q. Okay. And are there any basic standards for  
:25:43 21 conducting surveys?

:25:44 22 A. Sure. There's some fundamental ones. They're not the  
:25:47 23 only things that you want to do when you start using  
:25:50 24 specific techniques, but the fundamental concerns are,  
:25:54 25 first, to be sure that this is an issue that can or should

Scott - direct

1 be addressed by a surgeon. And obviously, if you want to  
2 know what surgeons perceive about a chart, you need to do  
3 some kind of survey now.

4 The second one is that you should sample from  
5 the appropriate universe, so you need to be asking the right  
6 people the questions, relevant people. So you need to find  
7 that population from the sample.

8 The third is that you need to have adequate  
9 controls for any other possible explanations you could have  
10 for the findings that you get. So they make -- in my study,  
11 for many example, surgeons will give you some reaction:  
12 What do we know, can we infer that those reactions are due  
13 to this chart or are they due to something else?

14 Fourth is, I believe the fourth one is that you  
15 need to ask clear and unbiased questions. And, of course,  
16 we make every attempt to do that, and biased is minimized or  
17 prevented in a number of ways. But to the extent you have  
18 an adequate control, that will also help you with that  
19 problem. If there are any problems, the control will help  
20 you even that out.

21 Fifth, you need to be sure that the responses  
22 are accurately recorded, and to the extent that you have to  
23 do any coding of those responses or categorizing of them,  
24 you need to do that in an accurate fashion.

25 And I believe the sixth is accurately analyzing

Scott - direct

:27:19 1 the data.

:27:20 2 Q. All right. Thank you, Dr. Scott.

:27:23 3 In looking at the PowerPoint that you prepared,  
:27:28 4 can you tell the jury again what you were asked to survey  
:27:32 5 with regard to Dr. Ott's chart that was circulated here and  
:27:36 6 shown, which the jury has seen many times already?

:27:39 7 A. Right. So as I understand it, some surgeons receive  
:27:43 8 this chart, and the question is, what impact, if any, would  
:27:48 9 it have an impact on someone's decision-making process, and  
:27:52 10 that's what we're -- I'm attempting to study here.

:27:55 11 Q. Okay. Thank you.

:27:56 12 Now, the next slide. Number 5, Mr. Splanski.

:28:01 13 Okay. Dr. Scott, did you determine which  
:28:04 14 population to survey when you were conducting your survey?

:28:08 15 A. Yes, I did.

:28:11 16 Q. And which population did you determine was the  
:28:13 17 appropriate population?

:28:14 18 A. Well, the appropriate population from my survey were  
:28:17 19 surgeons. In particular, surgeons in the AirSeal target  
:28:21 20 market. As you've just heard Dr. Ott say, he sent it to  
:28:25 21 surgeons, so that underscores the reason why we would talk  
:28:27 22 to surgeons.

:28:29 23 Surgeons are a critical part of decision-making  
:28:32 24 for any clinical product, clinical product meaning things  
:28:36 25 they're going to be using in their own practice, they

Scott - direct

1 obviously have a big say in what happens there.

2 So selling process is focused to a large degree  
3 on surgeons. Surgeons are a gatekeeper, if you will, for  
4 this kind of product. If the surgeon doesn't like it, then  
5 it's unlikely that anybody else is going to want to force it  
6 on them or to try to make them use it.

7 And especially a hospital administrator, the  
8 AirSeal product is relatively expensive, and there's no  
9 point in administrators wanting to buy expensive pieces of  
10 equipment if the surgeons don't want to use it.

11 So for all of these reasons as well as the  
12 surgeons being a target market and them being a recipient,  
13 for them to ask surgeons what they think.

14 Q. Thank you.

15 Next slide, Mr. Splanski.

16 Did you have an opportunity to review previous  
17 testimony that has been given here at this trial?

18 A. Yes, I did.

19 Q. And what did you determine with regard to that  
20 testimony?

21 A. Well, there's some pieces of it that were helpful.  
22 You will see here, we have two individuals. The one on the  
23 left is Mr. Spearman and he is the CEO and co-founder of  
24 Lexion. And on the right you have Rochelle Amann, who is  
25 the VP of sales and marketing for Lexion.

Scott - direct

1 And the trial transcript that I saw included a  
2 question to Mr. Spearman about who are the target customers  
3 for your product? And his answer was: Surgeons. 70,000  
4 surgeons out there.

5 Ms. Amann was also asked, who is the target  
6 customer for Lexion's product? And she said, essentially  
7 surgeons. Robotic surgeons, gynecologist surgeons,  
8 oncology, geriatric, urology, any type of minimally invasive  
9 doctor.

10 So this is important because it overlaps,  
11 obviously, with AirSeal's target market, and in particular  
12 now we have a list of the kinds of surgeons that we want to  
13 be sure to include in my sample.

14 Q. Thank you.

15 So is it fair to say that their trial testimony  
16 was consistent with your understanding of the population  
17 that should be surveyed to assist you in answering the issue  
18 you were asked to investigate?

19 A. Yes.

20 Q. Thank you.

21 So turning to the survey itself, did you  
22 determine what would constitute an adequate number of  
23 surgeons to participate in your survey?

24 A. Yes.

25 Q. Okay. And who recruited the panel participants?



Scott - direct

1 A. The panel was recruited by a company that specializes  
2 in healthcare and marketing and medical marketing research,  
3 and that group is called RECA Group. The RECA Group  
4 purchased two companies that I've used in the past. This  
5 industry is sort of consolidated. I used companies named  
6 Greenfield and one named GFK.

7 RECA bought their business in the  
8 healthcare industry, so they are now the leading research  
9 supplier in healthcare research. So they have access to the  
10 kind of people I needed to survey.

11 Q. Thank you.

12 And the next slide, please.

13 Okay. Dr. Scott, what does your slide that has  
14 been -- the slide on the screen show here? And there's a  
15 pointer if you would like to use it.

16 A. Okay.

17 Q. It's somewhere buried in that desk.

18 A. And I should have mentioned before the RECA Group  
19 recruited people to participate in an online survey, because  
20 just to get busy surgeons to participate, you have to do  
21 that.

22 Now, this slide is showing what respondents are  
23 going to see, and here we need to keep in mind that I'm  
24 going to split my whole entire of respondents into two  
25 groups. One group is going to see the chart you've seen

Scott - direct

:32:33 1 over and over again here, which is the chart on the left.

:32:37 2 This is the Lexion distributed chart, which has greater

:32:41 3 complication rates for AirSeal.

:32:43 4 So, for example, maybe the front row of the jury  
:32:48 5 here would see that chart.

:33:35 6 Q. So just to stop you again. This is a copy. Did you  
:33:41 7 use the same chart that Dr. Ott circulated?

:33:47 8 A. Yes.

:33:47 9 Q. That's what's being shown here. Is that correct?

:33:50 10 A. Yes.

:33:50 11 Q. Thank you.

:33:51 12 A. Yes. Complete with the ancillary slides and things  
:33:55 13 like that, it's the exact same. I didn't change this one.  
:33:59 14 This one comes from Lexion.

:34:01 15 If we go back to the other slide. The one on  
:34:05 16 the right, that one I created. Let's say the other half of  
:34:10 17 my survey group, my sample, is going to see that chart. And  
:34:15 18 that chart is what we call the control chart. That's what's  
:34:19 19 going to allow us to compare the responses we get for the  
:34:22 20 Lexion chart to a control chart.

:34:27 21 For example, in this chart -- let me explain it  
:34:30 22 to you a little bit.

:34:31 23 You can see that little chart looks exactly like  
:34:34 24 the Lexion chart. It's exactly like it, except for, I have  
:34:39 25 taken out what AirSeal contends is the false information.

Scott - direct

1                   So in this slide, AirSeal is not worse than the  
2 conventional trocars. It's about the same. And that's on  
3 purpose, because it's possible that anybody, any surgeon  
4 could get a chart on complication rates and that might cause  
5 some questions.

6                   It's possible that just being in a survey would  
7 have some effect. So you want to take all those into  
8 account by having another group that sees the exact same  
9 stimulus but for the bad information.

10                  So that's what this one is designed to do. It  
11 will control for -- for example, if there was a question  
12 that was biased, well, both groups would get it. So that  
13 couldn't be the source of any differential response, because  
14 you are all seeing the same thing and you are in the same  
15 study or seeing the same questions.

16                  The only difference is the complication rates  
17 for AirSeal.

18                  So any differences, we infer that any  
19 differences are coming from that difference on the chart.

20 Q.       Just to be clear, did all the surgeons that were  
21 surveyed view both charts as we see them up here?

22 A.       No, no. So in my survey, I have 398 surgeons. 204  
23 are going to see this chart. 194 are going to see this  
24 chart.

25                  If you saw the control chart, you have no idea

Scott - direct

1 there is even another chart because all you see when you  
2 take the survey is you see the chart you are assigned to.  
3 We should see, importantly, in the concept of control, it is  
4 important that we see that respondents are what we call  
5 randomly assigned to the stimulus. So if someone is invited  
6 to participate in the survey and they click on the link that  
7 says yes, I want to participate, then the computer will  
8 randomly assign that surgeon to one of these charts.

9 So that there is no systematic way somebody gets  
10 assigned to the chart. That's very important for scientific  
11 conclusions, is that people are randomly assigned to  
12 treatment. I haven't taken people from big hospitals and  
13 given this chart and people from small hospitals another  
14 chart. Everyone needs to be mixed up.

15 Once each group sees its own chart, then both  
16 groups are going to be asked some questions about the chart.  
17 The questions will be the same questions. So again, the  
18 only thing that differs between the two groups is that one  
19 saw the chart on the right, one saw the chart on the left.

20 Q. And to be clear, you said that both groups are going  
21 to be asked the same questions. Is that each group will be  
22 asked the same questions about only the charts they are  
23 viewing?

24 A. That's correct.

25 Q. So one views the Ott chart and answers the same set of

Scott - direct

:37:42 1 questions. Then a separate group views the control chart  
:37:46 2 you created but it also answers the same set of questions  
:37:50 3 but only relative to that control chart. Would that be  
:37:53 4 fair?

:37:53 5 A. That's correct.

:37:54 6 Q. Thank you. Mr. Splansky, please bring up SQ-371.

:38:07 7 Dr. Scott, please look on the screen here. Do  
:38:09 8 you recognize this document?

:38:11 9 A. Mostly because I have seen before. It's a little bit  
:38:16 10 difficult to read from here because it's so faint. But,  
:38:19 11 yes, I do recognize this.

:38:21 12 Q. What is this document?

:38:23 13 A. If a person was invited to participate in the survey  
:38:26 14 and they clicked on the link, then they would be taken to  
:38:29 15 the survey -- on the computer. And this is the first page  
:38:33 16 of that survey. Now, we will just point out that this first  
:38:38 17 page, this information really is for the RECA group so they  
:38:43 18 can assure that they have the right people for giving  
:38:46 19 answers, that is part of their validation process I don't  
:38:49 20 get that information. I never know anyone's name, anybody's  
:38:53 21 telephone number. Everybody is providing anonymous answers  
:38:58 22 to me.

:38:58 23 Q. Out of curiosity, at what point do you get this  
:39:01 24 information from these sheets right here?

:39:04 25 A. I never get that information. I only get the data to

Scott - direct

:39:07 1 my questions. It's very unprofessional to know the  
:39:12 2 identities of people that are providing information to you  
:39:15 3 in good faith.

:39:15 4 Q. So, Mr. Splansky, can you go to Page 13 of this  
:39:23 5 document, please.

:39:35 6 Dr. Scott, do you recognize this page?

:39:37 7 A. I do.

:39:38 8 Q. What is it, please describe it for the jury?

:39:41 9 A. Again, once you start the survey, you are going to be  
:39:46 10 asked a series of qualifying questions. For example, you  
:39:49 11 will be asked if you performed laparoscopic surgery or by  
:39:54 12 hand or robotically. You are going to be asked your  
:39:57 13 specialization. So we will be doing qualifications to be  
:40:00 14 sure that you are a surgeon who performs these kinds of  
:40:03 15 surgeries.

:40:04 16 Once we are sure that you qualify, then you will  
:40:07 17 start the main survey that we are really interested in.  
:40:10 18 This is the first beginning of that piece, which, if we blow  
:40:15 19 up the top part of it, you will see that that is some  
:40:19 20 general instructions to begin with. So it will just tell  
:40:22 21 the respondents, first of all, they have been told on a  
:40:26 22 previous slide, congratulations, you have qualified for the  
:40:29 23 survey. Now we will start. The next set of questions may  
:40:33 24 be about some information that you may or may not have seen  
:40:38 25 about whether the product has been introduced and so on.

Scott - direct

:40:41 1 You will see some general information here about  
:40:43 2 please look it over, take as long as you would like. When  
:40:47 3 you have finished looking at it, continue the survey, just  
:40:51 4 kind of generally getting into the survey.

:40:54 5 Then, if we get rid of that block, then you will  
:40:57 6 see, now this piece of information is coming up. And this  
:41:03 7 one happens to be the control chart.

:41:05 8 But if you were in the other group you would be  
:41:08 9 seeing the Lexion chart.

:41:11 10 Q. Thank you. Mr. Splansky, please go to Slide No. 8.

:41:19 11 In what form did you receive the data from the  
:41:23 12 survey that was sent out by RICA group?

:41:27 13 A. The respondents are going to input their own answers.  
:41:30 14 They are sitting at their computer taking it and they will  
:41:33 15 be clicking their answers or in some cases they need to  
:41:36 16 write out an answer if I ask them, what do you think, an  
:41:40 17 open-ended question. All that data the RICA group posted  
:41:44 18 the survey on their platform. And then we have kind of a  
:41:50 19 link to them. So as the data comes in on the computer, it  
:41:54 20 gets transferred to us, so that analyst for my firm takes  
:41:59 21 that data and does the analysis.

:42:01 22 Q. After the data was received, did you analyze the data?

:42:06 23 A. Yes, we did.

:42:08 24 Q. And from your analysis, did you make any key findings?

:42:16 25 A. Yes. There were written questions in the survey, and

Scott - direct

1 we will go over a few of them, those questions had to do  
2 with basically four conclusions that are key findings that  
3 we have in the survey. The first one is that respondents  
4 understood the message in the Lexion chart. That is very  
5 important, because you and I might have an opinion about  
6 what that chart says, but we are not surgeons. So what did  
7 the surgeons take away from this chart as its key message.

8 We finally decided what they thought the key  
9 message of this chart that Lexion was sending out.

10 The second question is that if complications  
11 rates, particularly the complication rates that were on this  
12 chart -- not every complication in the world -- but the  
13 complication rates on this chart were material to potential  
14 users. There was some influence on decisions.

15 The third is that if you saw the Lexion chart,  
16 you were less likely to say you would consider the AirSeal  
17 product than if you just got the neutral chart. That's how  
18 we know. We take their ratings and their ratings are much  
19 lower than the people who saw the control chart.

20 Then the fourth one is that Lexion's chart  
21 resulted in the surgeons being less likely to ask for  
22 additional trial or evaluation of the AirSeal product.

23 As we know, trial is an important next step.  
24 Once I think you are kind of interested in the product, the  
25 next step might be to get trial in your institution so you



Scott - direct

:43:54 1 can actually try it out in your environment. And the Lexion  
:43:57 2 chart viewers were less likely to want to pursue that next  
:44:00 3 step.

:44:00 4 Q. Let's take a closer look the four key findings. Next  
:44:05 5 slide, Mr. Splansky.

:44:09 6 Dr. Scott, is this your first key finding that  
:44:12 7 you just described for the jury?

:44:14 8 A. It is.

:44:17 9 Q. What does the slide show?

:44:20 10 A. So --

:44:21 11 Q. My apologies. We do have a pointer if you would like  
:44:24 12 to use it.

:44:33 13 A. You can see that there is a conclusion, Higher  
:44:35 14 complication rates with AirSeal. Well, that's kind of what  
:44:39 15 we are talking about, we were investigating. One of the  
:44:43 16 first questions, after they saw the chart, was what is the  
:44:46 17 main message that you take from this chart? It's completely  
:44:50 18 open-ended. I am not suggesting any response to you. You  
:44:54 19 just type in what you thought the main message was.

:44:57 20 You can see on the Lexion chart that 70 percent  
:45:00 21 of the respondents said the main message was something to do  
:45:03 22 with more problems, AirSeal, valveless, more/higher  
:45:10 23 complications, that kind of they thing. And 15 percent of  
:45:14 24 the respondents, and there is some overlap here, but another  
:45:17 25 15 percent mentioned something about specific complications.

Scott - direct

:45:22 1 So this means we are pretty sure that people who  
:45:24 2 saw the Lexion chart got the message that it was  
:45:29 3 communicating AirSeal has higher complication rates.

:45:31 4 Similarly, the control chart, which is important  
:45:34 5 to know, they understood the control chart, 75 percent said  
:45:38 6 the main message of the control chart was identical or  
:45:42 7 similar, no difference, comparable, I think on the order of  
:45:48 8 there is no difference between AirSeal and conventional  
:45:50 9 trocars.

:45:51 10 And ten percent mentioned low complications.

:45:54 11 Now, you might wonder why it's not a hundred  
:45:59 12 percent. I can just tell you, based on my four years  
:46:03 13 experience, I have never seen any communication to anybody,  
:46:06 14 including my own, to my students, that a hundred percent of  
:46:10 15 the people get it. A hundred percent, you never see  
:46:14 16 anything for a hundred percent. So 75 percent, 70 percent,  
:46:18 17 that's pretty good, excellent comprehension of a chart.

:46:22 18 So both charts communicate well their intended  
:46:26 19 message. Now we can be sure, if that is the message going  
:46:31 20 forward, that will be influencing other responses.

:46:35 21 Q. Why was that an important key finding?

:46:38 22 A. If people don't -- the first thing is, did people --  
:46:43 23 and I know AirSeal believes that that higher rate of  
:46:45 24 complications is incorrect. So did surgeons get correct  
:46:50 25 information? Yes, I did perceive it.

Scott - direct

:46:53 1 The other thing is it's very important to lay  
:46:56 2 the foundations we cite to the next questions. If you  
:46:58 3 haven't gotten the message then I can't attribute their  
:47:04 4 responses to that message. It is just very important to lay  
:47:07 5 that foundation that you would actually get what I think you  
:47:11 6 are getting.

:47:12 7 Q. Next slide, Mr. Splansky.

:47:16 8 What was your second key finding, Dr. Scott?

:47:19 9 A. The next finding is about whether the complication  
:47:21 10 rates that were shown on the chart are material to potential  
:47:26 11 users. And the question that relates to this is my  
:47:31 12 second -- it's not exactly the second question on the  
:47:35 13 survey. But our second key finding and second question we  
:47:39 14 are going to discuss is would the information on this chart,  
:47:42 15 that you have just seen, have any influence on your decision  
:47:45 16 to consider the AirSeal system for use in your surgeries.  
:47:49 17 And if we average the responses across both the control and  
:47:55 18 the Lexion chart people, the whole sample, we find that 56  
:48:00 19 percent said, yes, it would influence my decision.

:48:04 20 So over half, and you will see in a minute it's  
:48:07 21 much greater for the Lexion chart than the control chart.  
:48:11 22 Even the control chart, when you mention complication rates,  
:48:13 23 even if they are neutral, that is still something that would  
:48:18 24 potentially influence their decision. So complication rates  
:48:21 25 then do factor in.

Scott - direct

:48:23 1 Q. The lowest one, 16 percent, what did that show?

:48:37 2 A. What?

:48:37 3 Q. In terms of don't know for sure, 16 percent, what is  
:48:43 4 significance of that finding?

:48:44 5 A. It is very important to include this don't know  
:48:47 6 response as an alternative to respondents. If you don't,  
:48:49 7 then you could get people guessing, and if you are forced to  
:48:53 8 pick yes or no, it would or it wouldn't, then that is not  
:48:56 9 really fair to a respondent who says who said, well, I can't  
:49:00 10 really pick at this point.

:49:03 11 We give them the option of saying I don't know  
:49:05 12 or I'm not sure. If you have any hesitation about whether  
:49:09 13 that chart would or wouldn't affect your decision to  
:49:13 14 consider the AirSeal product, you can reflect that here.

:49:15 15 We had that at 16 percent, who said that.

:49:18 16 Q. Next slide, please. Dr. Scott, what was your third  
:49:25 17 key finding?

:49:29 18 A. The third key finding is, now we are going right into  
:49:34 19 the differential effects of the Lexion chart versus the  
:49:37 20 control chart. So the next question said, how would the  
:49:42 21 information in this chart influence your decision to  
:49:45 22 consider the AirSeal system for use in your surgeries? And  
:49:50 23 now you can see that the bars are now split between those  
:49:53 24 who saw the Lexion chart and it's supposed to be red, kind  
:49:59 25 of is red, and the control chart, which is down here in

Scott - direct

1 blue. So you will see that the people who saw the Lexion  
2 chart, the surgeons who saw the Lexion chart, 55.9 percent  
3 of them said they were less likely to consider the AirSeal  
4 product.

5 That's a big difference from the control group,  
6 where only 9.8 said that. This is what we would call  
7 statistically significantly different. So you use  
8 statistics to test the difference between these two portions  
9 to determine the probability that you have got this big of a  
10 difference by chance.

11 Our statistics say that it is with 95 percent  
12 confidence that it is not by chance, that these aren't just  
13 two different responses.

14 You will also see that there are people,  
15 particularly in the control group, 22 percent said they were  
16 more likely to consider, versus the Lexion chart at 14.2.  
17 At the bottom, this is also fairly dramatic, would not  
18 change of my consideration. That was fully 68 percent of  
19 the control group, we saw the neutral side, the neutral side  
20 wouldn't have any effect whether you want to consider it or  
21 not. And Lexion chart, 30 percent said it would not affect  
22 their consideration.

23 That is all the three comparison groups  
24 comparing the red and the blue in each of the three  
25 responses are significantly different.

Scott - direct

1 Q. Thank you.

2 Next slide, please.

3 Dr. Scott, what was your fourth -- well, fourth  
4 key finding that you are discussing here today?

5 A. Okay. Now we want to see if it would influence your  
6 decision or likely to consider, are there any actions that  
7 would be taken after seeing this chart, what actions would  
8 you be likely to take, and are there any differences in  
9 those actions between the people who saw the Lexion chart  
10 versus people who saw the control chart.

11 And so the question here is, finally, what  
12 actions, if any, would you be likely to take if you were  
13 evaluating the AirSeal System for use in your survey,  
14 surgeries, and you received this chart.

15 And for this question, there were a list of  
16 seven potential actions you could take plus other, so that  
17 if people have something else they wanted to say, they  
18 could. And those seven, looking at two specific ones here,  
19 we analyzed all of them, but we'll take the two here that  
20 are of most interest. And this one is particularly  
21 important. It says, "I would not consider the product any  
22 further. So once I see this chart, I really am not  
23 interested in hearing anymore." And that was true for  
24 25 percent, a quarter of the Lexion chart respondents, but  
25 true of only 10.8 percent of the control people. And the

Scott - direct

1 control people, it said, for example, well, if it's not  
2 better, if I want an improvement. Other people said, that's  
3 fine.

4 So here, you can see this difference is also  
5 statistically different (indicating).

6 And then, finally, a really important question  
7 for AirSeal is, one action, I would ask for additional trial  
8 and evaluation, meaning I would want to have it be evaluated  
9 in my hospital. In the Lexion chart, only 33.8 said they  
10 would like to have additional trial and evaluation versus  
11 the control, which was 50 percent, 50.5 percent. And this  
12 difference is also very significant.

13 Q. Okay. Thank you, Dr. Scott.

14 Next slide, please.

15 All right. So after analyzing the data that you  
16 obtained and then looking further and determining key  
17 findings that were discussed, did you come to any conclusion  
18 regarding the impact of the chart?

19 A. Yes. So what this chart shows, it's a little busy,  
20 but what it shows is it's a recap of our four key findings,  
21 right, that respondents understood the method. Complication  
22 rates shown were material to potential surgeons.

23 The Lexion chart had a negative effect on  
24 likely to consider the product. And the Lexion chart had a  
25 negative effect on the likelihood to ask for an additional

Scott - direct

1 trial or an evaluation of AirSeal.

2 So given that it is material and the Lexion  
3 chart has these negative influences, the basic conclusion  
4 down here in the bottom is, in addition, the complication  
5 rates are material, meaning having some effect on decisions,  
6 the AirSeal product would be harmed by this information.  
7 Anyone who received this now is likely to be negatively  
8 affected by it and that will be not a good thing for the  
9 AirSeal product.

10 At a minimum, they'll have to counter that  
11 information and they may lose control evaluating a product  
12 and these are not good results.

13 Q. And one last question: Have you ever seen evidence  
14 throughout the time you've spent in this litigation of  
15 Lexion having conducted a survey or consumer research  
16 on the particular issue or any issue involving the  
17 litigation?

18 A. I am not aware of one. I've not seen any.

19 Q. Thank you.

20 Do you hold all of your opinions that you've  
21 given here today within a reasonable degree of professional  
22 certainty in the fields of consumer surveys and consumer  
23 research?

24 A. I do.

25 MS. KRAFT: Thank you, Dr. Scott. I now pass



Scott - cross

1 the witness.

2 THE COURT: Thank you, Ms. Craft.

3 Mr. Reilly?

4 MR. REILLY: With your permission?

5 THE COURT: Sure, Mr. Reilly.

6 CROSS-EXAMINATION

7 BY MR. REILLY:

8 Q. Dr. Scott, good morning. I'm Paul Reilly. I'm with  
9 Baker Botts. I represent Lexion. We met a few months ago  
10 at your deposition.

11 Do you recall that?

12 A. Yes.

13 Q. Now, just to start off, you were not asked to do a  
14 survey on deception or confusion caused by this complication  
15 rate chart; is that correct?

16 A. That's correct. Not specifically.

17 Q. And you're not rendering an opinion here as to whether  
18 or not that chart is false; is that correct?

19 A. No, I'm not.

20 Q. Now, the control that you used and the test, if you  
21 would, Mr. Barnes, please put up that slide for me.

22 There are a number of articles below that chart;  
23 is that correct?

24 A. That's correct.

25 Q. And those articles are not presented to any of the

Scott - cross

:56:34 1 respondents; is that correct?

:56:35 2 A. That's correct. It's my understanding they were not  
:56:38 3 presented in the real world either.

:56:40 4 Q. How long does it take for your respondents to  
:56:45 5 participate in the survey and complete the your survey?

:56:48 6 A. Somewhere, we think it's around probably 15,  
:56:52 7 20 minutes, max.

:56:53 8 Q. And how long is the sales process approximately from  
:56:57 9 the beginning to the purchase, first being presented with  
:57:00 10 the product through the purchase?

:57:01 11 A. Well, like any medical device sales product, it can  
:57:07 12 be -- it can be shorter, but it can be very long.  
:57:10 13 Obviously, longer than 20 minutes.

:57:11 14 Q. And that sales process involves interactions between  
:57:15 15 sales representatives and the surgeons as well as other  
:57:18 16 hospital administrators; is that correct?

:57:20 17 A. It can, yes.

:57:21 18 Q. Typical, isn't it?

:57:22 19 A. Typical.

:57:23 20 Q. And you're aware that the complications chart that you  
:57:32 21 were testing is no longer in use. It's not being  
:57:35 22 distributed and it hasn't been for some time?

:57:38 23 A. I don't -- I didn't really investigate that. I think  
:57:41 24 I understood that they were not using it, but I don't know  
:57:44 25 when it was discontinued.

Scott - cross

:57:45 1 Q. Your control shows zero difference in complication  
:57:55 2 rates; is that correct?

:57:56 3 A. That's correct.

:57:56 4 Q. That's really going to be, have no moment for a  
:57:59 5 surgeon in making a decision; isn't that correct?

:58:01 6 A. Well, that's something we wanted to test here. You  
:58:05 7 know, you and I might think that it doesn't have any  
:58:08 8 informational value, but the surgeons, some of the surgeons  
:58:11 9 actually did find it to be informative, because for some  
:58:15 10 surgeons, they're looking for a product that's going to be  
:58:17 11 better than what they have. For other surgeons, they just  
:58:22 12 want reassurance that it's not going to be worse.

:58:24 13 You know, if you change -- if you change --  
:58:26 14 you, as a surgeon, you would have a system that's working  
:58:30 15 for you pretty well right now and you're pretty averse about  
:58:34 16 moving to something else unless you are sure it's going to  
:58:38 17 be okay.

:58:39 18 So I think that the data we have from the  
:58:42 19 individuals on our survey -- not everybody, of course, feels  
:58:45 20 the same way, but the majority of the respondents certainly  
:58:49 21 gave answers that reflected some impact of this chart.

:58:53 22 Q. Your study does not test for the effect of  
:58:57 23 complications chart on the ultimate decision to purchase the  
:58:59 24 AirSeal System; is that correct?

:59:01 25 A. I'm sorry. I didn't quite hear that.

Garcia - depo

1 Q. Your study does not test for the effect of the  
2 complications chart on the ultimate decision to purchase the  
3 AirSeal System; is that correct?

4 A. That's correct.

5 MR. REILLY: No further questions.

6 THE COURT: All right. Thank you, Mr. Reilly.

7 Any redirect?

8 MS. KRAFT: No redirect, Your Honor.

9 THE COURT: Thank you, Doctor.

10 MS. KRAFT: Thank you.

11 THE COURT: You are excused.

12 THE WITNESS: Thank you. Very.

13 (Witness excused.)

14 MS. PASCAL: Your Honor, SurgiQuest would like  
15 to call Mr. Joseph Garcia by deposition. Mr. Garcia was one  
16 of the sales representatives from Lexion Medical.

17 THE COURT: All right.

18 (The videotaped deposition of Joseph Garcia was  
19 played as follows.)

20 "Question: Did you have any customers tell you  
21 that they didn't notice a difference in the patient's  
22 outcome after using the Insuflo device?

23 "Answer: I had customers tell me that they  
24 didn't really believe in the science, that they didn't think  
25 Insuflo would provide any clinical benefit. And, yes, I

Garcia - depo

:00:45 1 did have customers tell me that they didn't really see a  
:00:48 2 difference. So to answer your question, yes.

:00:51 3 "Question: Did any of the material managers or  
:00:53 4 purchasing people within the hospital ever question the  
:00:55 5 clinical benefits to heating and humidifying the CO2 gas?

:01:01 6 "Answer: A lot of material managers aren't  
:01:03 7 clinical, so their primary, I guess, objective is to reduce  
:01:08 8 costs in the hospital rather than look at the clinical  
:01:10 9 benefits. So I don't think they could really give an  
:01:14 10 opinion on the clinical benefit of Lexion products. All  
:01:18 11 they look at is just the cost, how much you're adding onto  
:01:22 12 the case.

:01:23 13 "Question: So what was your sales strategy in  
:01:25 14 terms of convincing those people to purchase Lexion's  
:01:28 15 products?

:01:31 16 "Answer: You have to leverage the physician.  
:01:32 17 Doctor So-and so wants to use this product. This is the  
:01:38 18 cost. What have we got to do to get it ordered? So I would  
:01:44 19 leverage the -- the interaction I had with the physicians  
:01:47 20 and the -- and the OR directors, if that's the person that  
:01:50 21 made the decision.

:01:51 22 "Question: So what -- what would make it  
:01:55 23 unsuccessful of getting into a hospital even if you have  
:01:57 24 physicians requesting and successful trials?

:02:00 25 "Answer: So you're asking me why would I be

Garcia - depo

1 unsuccessful even if I had a physician that was requesting a  
2 product? It could be several reasons. One of the reasons,  
3 a main reason was GPO status. If you're not on a hospital's  
4 contract, buying contract, then they tend to steer away from  
5 purchasing products that are not on their contract.

6 "Question: Okay. So you were reporting on  
7 hospitals in your territory where you had had some  
8 competition with AirSeal or --

9 "Answer: I don't know if it was competition. I  
10 didn't really see AirSeal as competition, to be honest with  
11 you. I -- I thought they provided another benefit of  
12 features that -- that was not related to Lexion products.

13 "Question: What features do they -- did you  
14 believe the AirSeal provided them?

15 "Answer: I thought AirSeal -- and I may be  
16 wrong, but I thought AirSeal was there to maintain  
17 pneumoperitoneum and to create a clear picture while the  
18 doctor was operating. That's my -- my perception of what  
19 AirSeal was.

20 "Question: At the end of that last paragraph in  
21 your e-mail to Ms. Eberhart --

22 "Answer: Uh-huh.

23 "Question: -- you say, quote, 'I have spoke  
24 with robot coordinators, and they have mentioned the SQ reps  
25 are only promoting constant pneumo with smoke evacuation

Garcia - depo

1 with AirSeal.'" "

2 "Answer: Uh-huh, as I mentioned to you.

3 "Question: What did you mean by that?

4 "Answer: Like I said, when I was at the  
5 training and they showed they had the AirSeal at Lexion  
6 Medical, they were saying that it pulled in the air or that  
7 it provided, I think, warmth and humidity, was one of the  
8 claims that I've heard that AirSeal was making that I had  
9 never heard, that it provided warmth and humidity to the CO2  
10 gas, something I never heard from an AirSeal rep or a doctor  
11 tell me that's what they've heard.

12 "Question: All right. And in the eight years  
13 that you worked for Lexion, other than the three hospitals  
14 you identified in Exhibit 306, were there any other  
15 hospitals that you heard of that had even trialed the  
16 AirSeal System?

17 "Answer: One other hospital, I believe, in Salt  
18 Lake City, Utah. It was part of the Intermountain Health  
19 System. I believe they had the AirSeal, had purchased it.

20 "Question: Okay.

21 "Answer: I didn't see it, but I was told they  
22 had purchased it --

23 "Question: Okay. Any other --

24 "Answer: A while back. Years ago. That's in  
25 what I recall.

Danielewicz - dep.

:05:20 1 "Question: Okay. So in your entire eight years  
:05:22 2 in Lexion, would it be fair to say you only ran into the  
:05:27 3 AirSeal system in four different hospitals?

:05:29 4 "Answer: That would be fair.

:05:30 5 "Question: Okay. You mentioned a city, a  
:05:31 6 hospital in Salt Lake City that used the AirSeal system.  
:05:34 7 Were they also a Lexion customer?

:05:37 8 "Answer: No, they weren't. It was just a  
:05:39 9 hospital I was trying to sell to.

:05:41 10 "Question: So you do you think that -- so you  
:05:44 11 didn't lose any sales, really, in your territory due to the  
:05:47 12 AirSeal system, correct?

:05:48 13 "Answer: No."

:05:52 14 MS. PASCAL: Your Honor, Your Honor, SurgiQuest  
:05:54 15 would now like to call Mr. Robert Danielecwicz also by  
:06:00 16 deposition, also a Lexion sales representative.

:06:04 17 (Deposition of Robert Danielewicz read as  
:06:04 18 follows.)

:06:05 19 "Question: Did you come to learn why --

:06:49 20 "Answer: I learned that at least one AirSeal  
:06:51 21 was being purchased and being used; therefore insufflation  
:06:55 22 was not being used.

:06:57 23 "Question: Edward Hospital, on the next page,  
:07:03 24 so Dr. Chuck Miller, GYN, he used the Insuf flow and the  
:07:10 25 Pneuview at Lutheran General; is that what you're saying?



Danielewicz - dep.

:07:14 1 "Answer: Correct.

:07:15 2 "Question: And he was trying to bring the  
:07:16 3 devices into Edward Hospital, but, again, they were trying  
:07:19 4 to cut costs, especially robotic cases. So is that the  
:07:24 5 reason why you weren't able to make sales at Edward  
:07:28 6 Hospital?

:07:29 7 "Answer: I believe so.

:07:29 8 "Question: Are there any other reasons, other  
:07:35 9 than the fact that the hospital was trying to cut costs,  
:07:38 10 that you believe you were unable to sell Lexion products to  
:07:41 11 Edward Hospital?

:07:44 12 "Answer: I'm not sure.

:07:48 13 "Question: Okay. Going back to Exhibit 292, we  
:07:51 14 were looking at Mercy Hospital in the middle of the page?

:07:57 15 "Answer: Uh-huh.

:07:58 16 "Question: And you say that Synergy -- well,  
:08:01 17 you say, we are not on contract with them. What did you  
:08:09 18 mean by that?

:08:10 19 "Answer: Lexion Medical was not currently on  
:08:13 20 contract with the hospital. This use a GPO. Very common  
:08:17 21 practice for Lexion or any company to not be on contract  
:08:20 22 with a hospital's GPO. So just a -- just another hurdle to  
:08:25 23 get over.

:08:28 24 "Question: Okay. I'm going to butcher this  
:08:31 25 name, but Dr. Lutheranhausen had a bad experience with it in

Danielewicz - dep.

1 her last trial where visual -- visualization was not clear.

2 "What did you mean by that?

3 "Answer: She used Synergy three times. In the  
4 first two cases, everything went very well. Her  
5 visualization, meaning the scope did not fog, went very  
6 well. And the third case she had some fogging, and that  
7 stuck in her mind, the problem being there are so many  
8 different things that can affect lens fogging. If they take  
9 the camera out of the abdomen, the camera will get cold, and  
10 not Synergy or anything can prevent the fogging from  
11 happening.

12 "Question: Other than the problem with the  
13 fogging in that one case, did Northwest Community Hospital  
14 give you any other reason why they decided not to purchase  
15 the Synergy?

16 "Answer: No.

17 "Question: Isn't that exactly what you were  
18 doing with that complications chart?

19 "Answer: I was supplying information directly  
20 from my own from studies. I would supply that data to  
21 surgeons, and, once against again, they tell them derive  
22 their own conclusions.

23 "Question: But weren't you trying to make it  
24 look like the rates that were shown in those studies --  
25 weren't you, like, trying to generalize them and make it

Danielewicz - dep.

1 look like they were the rates for all instances of the  
2 AirSeal use?

3 "Answer: No. I was very clear that these were  
4 from the specific studies and that they should read the  
5 studies and draw their own conclusions.

6 "Question: At the top e-mail at the top of the  
7 page, you say, I actually had a doc tell me yesterday that  
8 he doesn't care if the visible smoke is still in the  
9 abdomen, in parentheses you say, I was explaining that the  
10 AirSeal only filters smoke particles but doesn't evacuate  
11 the invisible toxic gasses from smoke plume. Are you  
12 kidding?

13 "What -- what were you trying to convey there to  
14 Brittany? What did you understand the doctor to be telling  
15 you?

16 "Answer: Just as it says -- it can't be a  
17 concern of his. Every doctor has different concerns about  
18 different things.

19 "Question: Did any customer ever tell you that  
20 SurgiQuest had told them that the AirSeal filter removes  
21 hazardous gas?

22 "Answer: I don't recall that, no.

23 "Question: As a result of that and your  
24 understanding, do you -- are you aware that there are any  
25 risks associated with using the AirSeal system?

Harrison - depo.

:11:10 1 "Answer: I believe there are risks using the  
:11:12 2 AirSeal system in such an instance.

:11:16 3 "Question: And what are those risks?

:11:19 4 "Answer: Of bringing in, excuse me, outside  
:11:20 5 room air into the abdomen, the air is not -- non-sterile.  
:11:25 6 That brings in risk. The air is forced into the abdomen as  
:11:29 7 opposed to it just naturally flowing, for example,  
:11:32 8 contrasting and open. That air can get into places in  
:11:36 9 between the skin and peritoneum where doctors don't want  
:11:46 10 it."

:11:49 11 MS. PASCAL: Your Honor, we would now like to  
:11:53 12 call Xavier Harrison by deposition. He also was a sales  
:11:59 13 representative for Lexion Medical.

:12:04 14 (Deposition of Xavier Harrison read as follows.)

:12:05 15 "Question: When you worked for Lexion, did you  
:12:09 16 consider the SurgiQuest AirSeal system to be a competitive  
:12:12 17 product?

:12:13 18 "Answer: Indirect competition, yes.

:12:14 19 "Question: You said indirect competition?

:12:16 20 "Answer: Uh-huh.

:12:17 21 "Question: When you worked for Lexion, did you  
:12:19 22 consider the SurgiQuest AirSeal system to..."

:12:53 23 (Technical difficulties.)

:13:05 24 "Question: What do you mean by that?

:13:09 25 "When you worked for Lexion, did you consider

Harrison - depo.

1 the SurgiQuest AirSeal system to be a competitive product?

2 "Answer: Indirect competition, yes.

3 "Question: You said indirect competition?

4 "Answer: Uh-huh.

5 "Question: What do you mean by that?

6 "Answer: Insuflow is the only device on the  
7 market that humidifies and heats the CO2. Because of that,  
8 they are indirect. SurgiQuest or AirSeal is indirect  
9 competition.

10 "Question: Because the AirSeal does not heat  
11 and humidify the CO2?

12 "Answer: Does not heat and humidify the CO2,  
13 right.

14 "Question: But in selling Lexion's products,  
15 you were competing against the AirSeal system; correct?

16 "Answer: That's correct.

17 "Question: Okay. So Dr. Price's retirement was  
18 a reason for the lost opportunity at Mt. Carmel?

19 "Answer: That's -- yes, yes.

20 "Question: So was the delay in the larger  
21 sized Synergy ports a reason for the lost opportunity at VA  
22 Medical Hospital?

23 "Answer: Yeah, the length of time, yes.

24 "Question: Are you saying that the fact that  
25 there was turnover in the OR manager position at Mercy

Harrison - depo.

:14:18 1 Hospital was -- negatively impacted --

:14:21 2 "Answer: Yes.

:14:22 3 "Question: -- the ability to sell the Synergy  
:14:25 4 ports?

:14:26 5 "Answer: Yes.

:14:26 6 "Question: And that has nothing to do with  
:14:28 7 SurgiQuest's AirSeal, correct?

:14:30 8 "Answer: Correct.

:14:30 9 "Question: So the reason for your loss of  
:14:32 10 business at Christ Hospital was because they converted to  
:14:35 11 Stryker heated tubes?

:14:37 12 "Answer: Yes. Uh-huh.

:14:38 13 "Question: Are there any other reasons you  
:14:41 14 believe you lost sales to Christ Hospital?

:14:44 15 "Answer: That was it.

:14:46 16 "Question: Do you believe you were unable to  
:14:49 17 get an evaluation of the SurgiQuest device at Christ  
:14:51 18 hospital because of -- due to SurgiQuest's advertising of  
:14:56 19 the AirSeal system?

:14:57 20 "Answer: No, I don't think so.

:14:58 21 "Question: So do you think the delay in the  
:15:01 22 release of the larger sized Synergy ports combined with  
:15:06 23 Evelyn's retirement is the reason that you didn't get the  
:15:10 24 evaluation at Marion Health?

:15:15 25 "Answer: Yes, for the evaluation, yes.

Harrison - depo.

:15:17 1 "Question: So you're not aware of any instances  
:15:19 2 where a SurgiQuest representative has claimed that the  
:15:23 3 AirSeal humidifies and heats the CO2, correct?

:15:26 4 "Answer: No.

:15:26 5 "Question: Did any customer ever tell you that  
:15:29 6 they believed the AirSeal system heats and humidifies the  
:15:32 7 CO2?

:15:35 8 "Answer: No, I never heard that in my  
:15:38 9 territory.

:15:38 10 "Question: And then in 2014, it says growth  
:15:40 11 expectations. What's that about?

:15:43 12 "Answer: It's 400 -- it's the quote that,  
:15:46 13 basically, what they expected the territory -- or me to do  
:15:49 14 in the territory of \$437,291.

:15:52 15 "Question: And then below that, what does it  
:15:54 16 say?

:15:54 17 "Answer: A shortfall of \$43,759.

:16:00 18 "Question: So you didn't make the numbers?

:16:03 19 "Answer: I did not.

:16:08 20 "Question: And then following over on 2015  
:16:12 21 goals and forecasts --

:16:13 22 "Answer: Yes.

:16:14 23 "Question: -- it says, in order to accomplish  
:16:15 24 the hundred thousand dollars of new business we're talking  
:16:19 25 about. Is that your goal, projected goal, an additional

Harrison - depo.

:16:23 1 hundred thousand?

:16:24 2 "Answer: Yes. And I can't recall if that was  
:16:26 3 -- I think that was my personal goal. I can't recall that  
:16:29 4 was -- that was a stated quota. And I believe -- at this  
:16:32 5 point, I believe it was what I intended to accomplish.

:16:36 6 "Question: Okay. Did you accomplish that goal?

:16:39 7 "Answer: Well, I didn't finish out the year,  
:16:45 8 but I think I would have been short of that.

:16:49 9 "Question: Why do you think you were short?

:16:53 10 "Answer: Because of the loss of business.

:16:55 11 "Question: Why was -- why do you think you lost  
:16:58 12 business?

:16:58 13 "Answer: Because of the SurgiQuest AirSeal  
:17:00 14 system."

:17:09 15 MS. PASCAL: Your Honor, SurgiQuest would now  
:17:10 16 like to call Mr. Matthew Montano by deposition, also a  
:17:16 17 Lexion sales representative.

:17:22 18 (Deposition of Matthew Montano read as follows.)

:17:23 19 "Question: So approximately how many hospitals  
:17:25 20 or surgery doctors were in your sales territory?

:17:30 21 "Answer: Dozens.

:17:32 22 "Question: Dozens. Like more than a hundred?

:17:35 23 "Answer: Yes.

:17:35 24 "Question: How many did you actively reach out  
:17:51 25 to in connection with your job at Lexion, approximately?



Harrison - depo.

:17:55 1 "Answer: Approximately 50.

:18:01 2 "Question: And did you travel to each of those

:18:06 3 hospitals?

:18:07 4 "Answer: No.

:18:09 5 "Question: How many did you travel to,

:18:11 6 approximately?

:18:11 7 "Answer: Approximately 25.

:18:22 8 "Question: So customers who were more

:18:27 9 receptive, you visited more often?

:18:29 10 "Answer: Yes.

:18:29 11 "Question: And customers who were less

:18:31 12 receptive, you visited less often?

:18:35 13 "Answer: You could say that.

:18:36 14 "Question: Did you have any customers that used

:18:38 15 Insuflow but did not use a smoke evacuator at all?

:18:41 16 "Answer: Yes.

:18:41 17 "Question: Did those customers have any means

:18:44 18 of clearing the surgical smoke that is created during

:18:47 19 laparoscopic procedures?

:18:48 20 "Answer: Yes.

:18:52 21 "Question: How did they do that?

:18:55 22 "Answer: Opened a port.

:19:11 23 "Question: So they would open a port, and what

:19:16 24 would happen?

:19:17 25 "Answer: As I understood it, the pressure from

Harrison - depo.

:19:20 1 the abdomen would push the smoke out of the port.

:19:23 2 "Question: And where would the smoke get pushed  
:19:27 3 to.

:19:28 4 "Answer: Into the room.

:19:30 5 "Question: The operating room?

:19:31 6 "Answer: Yes. The Insuflow and Synergy were  
:19:37 7 pink.

:19:39 8 "Question: So you had some customers that  
:19:40 9 didn't like the fact that they were pink?

:19:42 10 "Answer: Yes.

:19:42 11 "Question: Anything else?

:19:46 12 "Answer: Yes. The Synergy did not have a  
:19:48 13 bladed tip.

:19:52 14 "Question: Did you ever speak to prospective  
:19:54 15 customers who were not convinced that there were benefits to  
:19:57 16 heating and humidifying insufflation gas?

:20:00 17 "Answer: I did.

:20:00 18 "Question: And how often did that happen?

:20:03 19 "Answer: Less than ten percent of my -- my time  
:20:15 20 selling."

:19:29 21 "Question: So for the rest of those who didn't  
:19:31 22 question it, how many regularly purchased Lexion's products?

:19:40 23 "Answer: A low percentage.

:19:42 24 "BY MS. ACQUISTA:

:19:46 25 "Question: What is a low percentage?

Harrison - depo.

:19:53 1 "Answer: 20 percent.

:19:53 2 "Question: What about Memorial Sloan Kettering,

:19:57 3 were they a customer -- was that in your territory?

:20:00 4 "Answer: It was.

:20:01 5 "Question: And what Lexion products did

:20:04 6 Memorial Sloan Kettering purchase?

:20:05 7 "Answer: Insuflow.

:20:06 8 "Question: Did sales of Insuflow to Memorial

:20:10 9 Sloan Kettering change at all over time?

:20:10 10 "Answer: Yes.

:20:13 11 "Question: In what way?

:20:16 12 "Answer: They increased and then decreased.

:20:18 13 "Question: At what point did they increase?

:20:23 14 "Answer: Approximately October of 2014.

:20:24 15 "Question: And do you have an understanding of

:20:26 16 why they increased?

:20:36 17 "Answer: No.

:20:37 18 "Question: And at what point did they

:20:39 19 decrease -- actually, before I ask you that.

:20:43 20 "How much did they increase in October 2014?

:20:47 21 "Answer: I would have to -- I don't -- I don't

:20:49 22 know. It has been a long time.

:20:50 23 "Question: And at what point did the sales of

:20:52 24 Insuflow to Memorial Sloan Kettering decrease?

:20:57 25 "Answer: I would guesstimate around April of

Harrison - depo.

1 the following year, March or April.

2 "Question: Of 2015?

3 "Answer: Yes.

4 "Question: Did the hospital provide you a  
5 reason of why they decreased?

6 "Answer: Yes.

7 "Question: What was the reason?

8 "Answer: Cost.

9 "Question: Following the statements that we  
10 just looked at in your e-mail to Shelly, you say, quote,  
11 'Surprisingly, the CO2/air conversation had not had as much  
12 of an impact as I would have imagined.'"

13 What do you mean by 'the CO2 air conversation'?

14 Answer: The AirSeal is a CO2/air insufflators.

15 "Question: And what did you mean when you said  
16 it had not had as much of an impact as I would have  
17 imagined?

18 "Answer: I am not a physician, but knowing what  
19 I know about CO2 being the, quote, 'gold standard' for the  
20 preferred media for insufflation, when you introduce a  
21 CO2/air insufflator, it didn't -- it didn't seem to resonate  
22 with a lot of the surgeons that I would deal with. I  
23 thought they would take it more seriously, but it didn't  
24 really seem to affect their decision. Ultimately, they  
25 bought the -- the AirSeal, so --

Heidenreich - depo

:23:03 1 "Question: Did St. Mary's hospital purchase an  
:23:06 2 AirSeal System?

:23:10 3 "Answer: They did.

:23:11 4 "Question: And did it affect your sales to them  
:23:13 5 of the Synergy device?

:23:18 6 "Answer: No.

:23:18 7 "Question: Are there any hospitals in your  
:23:21 8 territory where you believe you lost business because  
:23:23 9 SurgiQuest was making false claims about what its product  
:23:26 10 could do?

:23:30 11 THE WITNESS: I don't know."

:23:39 12 (End of videotaped deposition.)

:23:42 13 MS. PASCAL: Your Honor, these would be the last  
:23:47 14 one of these. SurgiQuest would like to call Ms. Kassi  
:23:50 15 Heidenreich, also a Lexion territory sales representative.

:23:54 16 THE COURT: All right.

:23:55 17 MS. PASCAL: Thank you.

:23:55 18 (The videotaped deposition of Kassi Heidenreich  
:23:57 19 was played as follows.)

:23:57 20 "Question: Okay. And what was discussed in  
:23:59 21 regards to -- well, let me ask you this: Do you consider  
:24:01 22 the SurgiQuest AirSeal System to be a competitive product to  
:24:09 23 the Synergy device?

:24:11 24 "Answer: I consider them to be a competitive  
:24:13 25 device in the sense that if you're using AirSeal, there are

Heidenreich - depo

:24:16 1 three of my products that you cannot use in conjunction.

:24:21 2 "Question: Which three products?

:24:25 3 "Answer: Well, let's -- let's just say all of  
:24:27 4 them, I suppose, then. There's no way for you to use  
:24:32 5 AirSeal, that I'm aware of, in conjunction with any of my  
:24:37 6 products. You're either going to use AirSeal or you're  
:24:42 7 going to use Lexion Medical products in that -- comparing  
:24:47 8 those two.

:24:48 9 "Question: When you started with Lexion,  
:24:50 10 was the Franciscan Health Alliance already purchasing  
:25:01 11 Insuflow?

:25:01 12 "Answer: Yes.

:25:03 13 "Question: And do they still purchase Insuflow  
:25:06 14 today?

:25:06 15 "Answer: Yes.

:25:09 16 "Question: Has their sales volume with respect  
:25:10 17 to the Insuflow gone up or down during your tenure with  
:25:13 18 Lexion?

:25:14 19 "Answer: It has gone down.

:25:15 20 "Question: Which hospitals within the  
:25:18 21 Franciscan Health Alliance are presently using Insuflow?

:25:27 22 "Answer: St. Elizabeth's.

:25:29 23 "Question: Any others?

:25:35 24 "Answer: Huh-uh.

:25:36 25 "Question: Is the reason that the sales volume

Heidenreich - depo

:25:38 1 went down because some of those accounts converted to  
:25:43 2 Synergy?

:25:44 3 "Answer: No. St. Elizabeth's specifically went  
:25:47 4 down when they started using the AirSeal.

:25:52 5 "Question: Okay. Other than the use of the  
:25:54 6 AirSeal System, are there any other reasons that you believe  
:25:57 7 you lost Insuflow business at St. Elizabeth's?

:26:00 8 "Answer: No.

:26:02 9 "Question: So would you consider the Buffalo  
:26:05 10 filter to be competitive to the PneuView and Very Clear?

:26:10 11 "Answer: I would consider them to be a  
:26:12 12 competitor in the sense that you're using the Buffalo  
:26:15 13 filter, you would not be using the PneuView.

:26:21 14 "Question: Okay. And the next paragraph is for  
:26:23 15 Insuflow.

:26:24 16 "Answer: Mm-hmm.

:26:25 17 "Question: Guardian and you have listed there  
:26:29 18 Stryker heated tubing or Stryker regular insufflation  
:26:34 19 tubing.

:26:34 20 "Answer: Right.

:26:35 21 "Question: Or, I'm sorry, would you tell a  
:26:38 22 customer that they could use the Synergy device in place of  
:26:40 23 the AirSeal device?

:26:41 24 "Answer: You can't use the two together; so I  
:26:43 25 would say, for insufflating in a procedure, you would use

Heidenreich - depo

:26:46 1 Synergy over AirSeal, yes.

:26:52 2 "Question: Do you believe that you lost sales  
:26:54 3 or were unable to make sales at Jennie Stuart Medical Center  
:26:59 4 due to SurgiQuest advertising of the AirSeal System?

:27:04 5 "Answer: I didn't lose sales there.

:27:07 6 "Question: When you saw the cost analysis  
:27:08 7 where they said humidifier not needed, did you understand  
:27:11 8 that to mean that the AirSeal System heats and humidifies  
:27:15 9 the CO2?

:27:16 10 "Answer: No.

:27:16 11 "Question: Have any of your customers told you  
:27:21 12 that SurgiQuest represented to them that the AirSeal System  
:27:25 13 heats and humidifies the CO2?

:27:27 14 "Answer: No.

:27:28 15 "Question: Have any of you customers told you  
:27:30 16 that they believe the AirSeal System heats and humidifies  
:27:33 17 the CO2?

:27:35 18 "Answer: No.

:27:36 19 "Question: Have any of your customers told you  
:27:38 20 that they believe the AirSeal filter removes 100 percent of  
:27:41 21 the carcinogenic gasses contained in surgical smoke?

:27:46 22 "Answer: Not in that manner, no.

:27:47 23 "Question: In a different manner?

:27:49 24 "Answer: I think that they think that they  
:27:50 25 don't need a smoke evacuator. So I don't know where they



Heidenreich - depo

1 would draw that conclusion from. I'm just saying that  
2 they -- they say, we don't need a smoke evacuator.

3 "Question: I want to address your attention to  
4 Plaintiff's Exhibit 264 again. And if you could just read  
5 for me, there's a July 8, 2013, e-mail from Carl Geisz to  
6 several others on an e-mail string. Could you just read  
7 what it says, what he wrote.

8 "Answer: Are you talking about -- I'm sorry.

9 "Question: Starts with, 'See attached.'

10 "Answer: Okay, okay. (Reading). See attached  
11 cost -- or sample cost comparison from SurgiQuest. It  
12 states that, quotation, 'CO2 warmer/humidifier,' end quote,  
13 not needed for both a robotic prostatectomy and a robotic  
14 hysterectomy. Their whole cost justification is going after  
15 our current business based upon not needing a CO2  
16 warmer/humidifier. Their cost justification numbers don't  
17 work if they remove the cost of Insuflow.

18 "'The AirSeal does not actively humidify or warm  
19 the CO2. The high recirculating CO2 gas flow in and out of  
20 the patient must be constantly cooling the patient. And  
21 they have no method for introducing moisture. The only  
22 input to the system is dry and cool CO2 (and maybe some room  
23 air). What a joke?'"

24 "Bridget mentioned yet that when speaking with a  
25 former sales manager of surge SurgiQuest, he stated that one

Heidenreich - depo

:29:30 1 of their older designs definitely allowed for patient  
:29:33 2 contamination of the insufflator. I don't believe that  
:29:36 3 ever -- that ever had a recall and any filing about this  
:29:39 4 with the FDA regarding potential contamination.

:29:45 5 "Question: No, understood. I meant the  
:29:47 6 statements that were being made by --

:29:49 7 "Answer: Oh, I'm sorry.

:29:50 8 "Question: -- Mr. Geisz on the front page. Do  
:29:53 9 you agree with those statements that he's making based on  
:29:56 10 your understanding of the devices?

:29:58 11 "Answer: Absolutely. Yes.

:30:00 12 "Question: Does the Insuflow device help  
:30:02 13 maintain pneumo stability?

:30:04 14 "Answer: Not the Insuflow.

:30:05 15 "Question. Does the Insuflow device evacuate  
:30:08 16 surgical smoke?

:30:09 17 "Answer: No.

:30:10 18 "Question: Does the Insuflow device allow a  
:30:12 19 surgeon to operate at lower pressures?

:30:17 20 "Answer: Not the Insuflow."

:30:19 21 (End of videotaped deposition.)

:30:25 22 MS. REINCKENS: Your Honor, SurgiQuest calls Dr.  
:30:28 23 Keith Ugone.

:31:03 24 ... KEITH RAYMOND UGONE, having been duly  
:31:11 25 sworn as a witness, was examined and testified as

Ugone - direct

:31:13 1 follows ...

:31:24 2 MR. REINCKENS: Your Honor, may we approach with  
:31:25 3 the binder?

:31:26 4 THE COURT: Yes.

:31:27 5 MR. RYAN: Thank you.

:31:43 6 (Ms. Reinckens handed a binder to the witness.)

:31:56 7 THE COURT: Good morning, doctor.

:31:57 8 THE WITNESS: Good morning.

:31:59 9 THE COURT: Or afternoon. Good afternoon.

:32:02 10 THE WITNESS: You're correct.

:32:04 11 THE COURT: Counsel?

:32:05 12 MS. REINCKENS: May I proceed?

:32:06 13 THE COURT: Yes.

:32:06 14 MS. REINCKENS: Thank you.

:32:07 15 DIRECT EXAMINATION

:32:08 16 BY MS. REINCKENS:

:32:08 17 Q. Dr. Ugone, would you please introduce yourself to the  
:32:11 18 jury?

:32:11 19 A. Yes. As I mentioned, my name is Keith Raymond Ugone.  
:32:16 20 The last name is spelled U-g-o-n-e.

:32:18 21 MS. REINCKENS: Mr. Splanski, can you please  
:32:20 22 pull up the second slide, please.

:32:20 23 BY MS. REINCKENS:

:32:23 24 Q. Dr. Ugone, did you prepare the slides that you will be  
:32:25 25 presenting to the jury here today?

Ugone - direct

:32:26 1 A. Yes, I did.

:32:27 2 Q. And can you please explain why you are here today, Dr.  
:32:32 3 Ugone.

:32:32 4 A. Well, I'm really here for the three reasons. Earlier  
:32:36 5 in the trial the jury has heard the testimony from one of  
:32:42 6 Lexion's experts, Mr. Andrien, and he presented what we  
:32:47 7 call the claim damages because of the electrical conduct,  
:32:51 8 why we're here in this trial. And what I'm going to do  
:32:54 9 is evaluate for the jury the presentation he made as to  
:33:00 10 claimed damages and point out some flaws in the calculations  
:33:03 11 that he did. So that's one of the first things I'm going to  
:33:06 12 do.

:33:06 13 What I also am going to do is provide an  
:33:08 14 alternative number if the jury were to find liability in  
:33:15 15 this case. I'm going to present an alternative number to  
:33:17 16 the number that Mr. Andrien presented.

:33:19 17 And then, finally, and I will explain this a  
:33:22 18 little bit more, I will have a discussion on what's known as  
:33:26 19 a permanent injunction and whether it's warranted in this  
:33:30 20 case or not.

:34:15 21 Q. Dr. Ugone, what do you do for a living?

:34:18 22 A. Actually, I am an economist. I have kind of a fancy  
:34:25 23 description of what I do. But I call myself a forensic  
:34:30 24 economist and damage quantifier.

:34:32 25 Q. Can you please explain what a forensic economist and

Ugone - direct

:34:35 1 damages quantifier does?

:34:37 2 A. Well, in terms of the work that I do, there is this  
:34:40 3 forensic part. In other words, it is not uncommon that  
:34:44 4 companies get into a dispute, much like SurgiQuest and  
:34:47 5 Lexion here, and so the forensic part is, I try to figure  
:34:52 6 out, well, what happened, and what would have happened in  
:34:58 7 the absence of what's being alleged in the case, the alleged  
:35:00 8 wrongful conduct. That is the forensic part.

:35:03 9 Q. And what about the damages quantification part?

:35:06 10 A. That is ultimately, if it is determined that harm has  
:35:09 11 taken place, someone has to determine what that number is.

:35:14 12 So I would have to do what's called quantifying  
:35:17 13 damages.

:35:18 14 So a forensic economist tries to figure out what  
:35:21 15 happened in the marketplace. What would have happened if  
:35:23 16 there wasn't the alleged wrongful conduct? And then if  
:35:26 17 there is harm, what's the dollar amount of that harm.

:35:29 18 Q. Now turning to your background and experience.

:35:33 19 Mr. Spalsnky, can you please pull up the third  
:35:39 20 slide.

:35:40 21 Doctor, would you tell us about your educational  
:35:42 22 background, please?

:35:43 23 A. Yes. So I received a Bachelor's degree in economics  
:35:45 24 from the University of Notre Dame in 1977. Then I received  
:35:51 25 a Master's degree in economics from the University of

Ugone - direct

1 Southern California in 1979. I don't know if you are a  
2 football fan. If you are, that is kind of a contradiction,  
3 that I went to U.S.C. and Notre Dame.

4 And I got my Ph.D. in economics from Arizona  
5 University, my Ph.D. in economics in 1983. So I went to  
6 college for ten straight years.

7 Q. What did you do after you got your Ph.D.?

8 A. After I got my of Ph.D. I taught at one of the  
9 California State system schools, that is in the San Fernando  
10 Valley, at Los Angeles, full time and I also taught in the  
11 evening some part-time classes as well.

12 But that was from 1983 to '85. In 1985 I joined  
13 PriceWaterhouse Coopers. I want to be a little careful. I  
14 say they count the Academy Award ballots, but I am a little  
15 timid to say that right now. I was there for 18 years, from  
16 1985 to 2003.

17 From the very beginning of 2004, I joined  
18 Analysis Group, and I am with them today. That is about 13  
19 years at Analysis Group.

20 Q. What do you do at Analysis Group?

21 A. My title is a managing principal. So I have firm-wide  
22 responsibilities with the company, helping set direction,  
23 policy, the nature of work we will perform for clients. But  
24 I also run the Dallas Office of Analysis Group, from Dallas,  
25 Texas.

Ugone - direct

:37:30 1 Finally, in addition to my management  
:37:32 2 responsibilities, I do what's called client service work, so  
:37:36 3 I do consulting for clients when I am retained to do so.

:37:39 4 Q. Have you been qualified to testify as a damages expert  
:37:43 5 in other cases before this one?

:37:45 6 A. I have. In fact, the first time I testified was in  
:37:49 7 like June or July of 1990. It's been a long time.

:37:53 8 Q. Have you performed economic and damages-related work  
:37:57 9 in false advertising cases before?

:37:59 10 A. I have, yes.

:37:59 11 Q. Could you briefly just give us some examples of such  
:38:04 12 cases?

:38:05 13 A. Well, I have worked on a number of different cases.  
:38:07 14 One fun case I worked on was, if you have heard of the  
:38:11 15 product White Strips, the strips you put on your teeth to  
:38:15 16 whiten, there was a big dispute between Colgate and Procter  
:38:18 17 & Gamble. There were some allegations of false advertising  
:38:24 18 related to the White Strips product. So I worked on that  
:38:26 19 case.

:38:30 20 I am working on a case right now dealing with  
:38:33 21 pregnancy test strips for the Clear Blue product, if you  
:38:37 22 have heard of that.

:38:38 23 And I have also worked on false advertising  
:38:41 24 cases dealing with scouting cameras they put out in the  
:38:45 25 woods to try to take pictures of animals as they go by.

Ugone - direct

:38:49 1 Q. Have you evaluated the types of damages that are at  
:38:52 2 issue in this case in your other work in the past?

:38:55 3 A. Yes.

:38:55 4 Q. Have you worked on cases before where the products at  
:39:00 5 issue were medical devices?

:39:01 6 A. I have worked on a fairly large number of  
:39:04 7 medical-device-related cases, including laparoscopic  
:39:08 8 instruments that go down into the trocar. So I have worked  
:39:11 9 on cases involving instruments. I have worked on cases  
:39:15 10 involving trocars. I have worked on other medical device  
:39:18 11 cases as well.

:39:19 12 Q. How long have you been a testifying expert?

:39:21 13 A. 1990 was the first time I testified.

:39:23 14 Q. Is Analysis Group being paid for your time here today?

:39:27 15 A. So Analysis Group does some kind of billing rate and  
:39:32 16 the firm is getting paid for my time.

:39:34 17 Q. What is the rate that Analysis Group charges for your  
:39:37 18 work here today?

:39:38 19 A. So Analysis Group, for all the work that I do, charges  
:39:42 20 \$625 an hour.

:39:44 21 Q. And is Analysis Group's compensation dependent upon  
:39:48 22 the opinions you give and the outcome of the matter?

:39:52 23 A. No.

:39:55 24 MS. REINCKENS: Your Honor, I offer Dr. Ugone as  
:39:58 25 an expert witness in economics and damages.



Ugone - direct

:40:00 1 MR. WILLE: No objection, Your Honor.

:40:02 2 THE COURT: The doctor is accepted as an expert  
:40:04 3 in those fields.

:40:05 4 BY MS. REINCKENS:

:40:06 5 Q. Dr. Ugone, let's turn now to your assignment in this  
:40:10 6 case, please.

:40:11 7 In evaluating Mr. Andrien's damages-related  
:40:14 8 opinions, did you provide any of your own opinions regarding  
:40:17 9 what damages should be?

:40:18 10 A. Yes, I did. Mr. Andrien provided three different  
:40:25 11 damages figures to the jury. I have evaluated each of  
:40:30 12 those, and I have provided alternative numbers as well.

:40:33 13 Q. Mr. Splansky, can you please pull up the fourth slide.

:40:39 14 Dr. Ugone, can you briefly tell the jury what  
:40:41 15 you did to prepare for your opinions that you will be giving  
:40:44 16 here today?

:40:45 17 A. Yes. So when I was retained, it's important to  
:40:50 18 receive documents, to understand what the case is about.  
:40:56 19 Ultimately, as an economist and a damage quantifier, I am  
:40:59 20 going to be working with numbers. For example, I looked at  
:41:03 21 SurgiQuest documents, including the financial statements,  
:41:06 22 their sales records, the same thing with Lexion in terms of  
:41:10 23 their financial statements and their sales records.

:41:13 24 I looked at various expert reports, Mr. Lee --  
:41:17 25 Dr. Lee, Dr. Ramirez, Mr. Andrien's expert report. There

Ugone - direct

1 was also depositions to understand some of the documents  
2 that I reviewed.

3 I talked to surgeons and also discussed certain  
4 aspects of the case with Mr. Tegan. I attended portions of  
5 the trial.

6 It was well rounded in terms of the documents I  
7 got in order to put it all together in the reports that I  
8 had issued. So I did issue reports in this case.

9 Q. Are you prepared today to discuss and explain your  
10 findings to the jury?

11 A. Yes.

12 Q. Mr. Splansky, can you please pull up Slide 5.

13 Let's turn to Mr. Andrien's lost profits damages  
14 now. Dr. Ugone, can you briefly describe Mr. Andrien's  
15 opinions regarding Lexion's lost profits damages?

16 A. Yes. Well, Mr. Andrien is claiming that in the  
17 absence of the alleged wrongful conduct of SurgiQuest that  
18 Lexion would have made additional Insuflow and Synergy sales  
19 and would have made additional profits on those products. I  
20 believe his lost profits number was about 22.1 million  
21 dollars.

22 Q. Do you agree with Mr. Andrien's opinions?

23 A. No, I do not.

24 Q. Mr. Splansky, can you please pull up the next slide.

25 Please tell the jury why you do not agree with

Ugone - direct

1 Mr. Andrien's opinions.

2 A. There is a lot going on in this chart. But I think  
3 there is two main points I want to make and then there is  
4 some subpoints.

5 If you look at the upper left, in fact, you see  
6 the title of the chart, it says Flaws in Mr. Andrien's  
7 calculation of Lexion's Claimed Lost Profits Damages, but  
8 immediately below that, there is what I would call a lack of  
9 an economic causal connection.

10 What does that mean? That if you are going to  
11 evaluate damages, if you are going to say somebody has been  
12 harmed monetarily, you can't just look at whether sales have  
13 gone down. You have got to say, is there this causal  
14 connection, economic causal connection.

15 I am not giving a legal opinion. I am giving an  
16 economic opinion as to whether you can follow the links from  
17 whatever the alleged wrongful conduct is to a diminishment  
18 in sales.

19 And one of the major points I am making is that  
20 Mr. Andrien did not establish this economic causal link  
21 between the alleged wrongful conduct and Lexion's lost sales  
22 and the magnitude that he is giving.

23 Remember, ultimately, he has some very, very  
24 large numbers, that he is saying of what were AirSeal sales  
25 that would have transferred over to Insuflow and Synergy is

Ugone - direct

:44:22 1 a very big percentage of that. We will talk about that.

:44:25 2 Q. It is your opinion that Dr. Andrien has failed to  
:44:30 3 establish such a direct economic causal link?

:44:33 4 A. That's correct.

:44:33 5 Q. Dr. Ugone, why do people buy the AirSeal?

:44:37 6 A. As we have seen at trial here, there is a number of  
:44:41 7 reasons why people buy the AirSeal, but it includes the  
:44:44 8 stable pneumo attribute, smoke evacuation, and also the  
:44:51 9 valveless port.

:44:53 10 So we have heard about that from doctors, we  
:44:56 11 have seen brochures. But the point is, the reason we are  
:45:01 12 bringing that up now, under the box where it says a lack of  
:45:05 13 economic causal connection, I think we want to make sure we  
:45:11 14 understand why there is the demand for the AirSeal. It is  
:45:14 15 primarily for those three key benefits that I just  
:45:17 16 mentioned.

:45:17 17 Q. Did you consider any marketing materials that reflect  
:45:20 18 that these three key benefits are the drivers of purchase  
:45:23 19 for the AirSeal?

:45:24 20 A. I did. We don't want to jump ahead here, but I have a  
:45:30 21 slide on it. Ultimately, for example, if you look at the  
:45:33 22 AirSeal brochure, it lists those three attributes and  
:45:37 23 benefits in addition to others.

:45:38 24 Q. Mr. Splansky, can you please pull up Slide 9.

:45:42 25 A. So we see it here, yes.

Ugone - direct

:45:44 1 Q. This is what you were just referring to, the brochure?

:45:47 2 A. Yes. So the stable pneumo, continuous smoke

:45:50 3 evacuation and the valveless access.

:45:52 4 Q. Mr. Splansky, can you please pull up Slide 12. Dr.

:46:01 5 Ugone, what does this slide show?

:46:03 6 A. This even kind of reinforces what I was saying. So we

:46:08 7 see it in the brochures. We have heard it from the trial

:46:11 8 testimony. And we even see it as some of the

:46:15 9 correspondence, e-mail and documents within Lexion, these

:46:19 10 same concepts.

:46:19 11 So if you see the first one, which was an

:46:23 12 e-mail, you can see that it says, AirSeal over Insuflow --

:46:28 13 and I accidentally touched the screen -- it says it does a

:46:34 14 tremendous job of maintaining pneumo and keeping the field

:46:37 15 clear during the procedure.

:46:39 16 Again, even the competition, Lexion, was

:46:41 17 admitting that those are the benefits of the AirSeal.

:46:43 18 Q. And, Mr. Splansky, can you please go to Slide 13.

:46:54 19 Doctor, what did this slide show?

:46:57 20 A. There was some trial testimony, both from the

:47:03 21 Surgiquest CEO and a former Lexion territory manager, that

:47:10 22 speaks to some of the benefits in this case. They are

:47:12 23 talking about the AirSeal is especially desirable for

:47:16 24 robotic-assisted surgeries. And the CEO of SurgiQuest said,

:47:24 25 "When you were designing the system, did you

Ugone - direct

:47:28 1 speak to robotic surgeons when you were designing the system  
:47:31 2 to ask them if they found that type of feature to be  
:47:35 3 helpful?"

:47:36 4 And he is saying, "Absolutely."

:47:39 5 "And did the SurgiQuest" -- this is Ms.  
:47:42 6 Moriarty, who is a former Lexion territory manager.

:47:48 7 "Question: You saw that surgeons wanted the  
:47:50 8 SurgiQuest specifically for robotic cases?

:47:53 9 And the answer is, "That's probably true."

:47:56 10 But it's because of the attributes we have been  
:47:59 11 seeing at trial, the stable pneumo, the smokeless  
:48:03 12 evacuation, and the valveless port.

:48:05 13 Q. Dr. Ugone, is it fair to say that this evidence has  
:48:05 14 informed your opinion?

:48:09 15 A. Yes.

:48:09 16 Q. Can you please explain how so for the jury?

:48:11 17 A. What I was trying to understand, first off, is why do  
:48:16 18 people buy the AirSeal. And I think there is an abundance  
:48:20 19 of evidence that we have seen and that the jury has seen at  
:48:23 20 trial as to the reasons why people buy the AirSeal.

:48:27 21 Q. Does this evidence confirm that there is a lack of  
:48:31 22 economic causal connection?

:48:32 23 A. Right. So this is kind the hard part of a damages  
:48:40 24 calculation. What you need to sort of try to figure out is,  
:48:43 25 let's just take the AirSeal, so the question is, in the

Ugone - direct

1 absence of the alleged wrongful conduct, so you took that  
2 away, would AirSeal's sales have gone down? And this  
3 answers the question with a no because people were buying  
4 the AirSeal because of the stable pneumo, the smoke  
5 evacuation, and the valveless port.

6 So if you take away the alleged wrongful conduct  
7 and the alleged statements that are being alleged in this  
8 case by Lexion, you don't see a situation where people would  
9 have stopped suddenly buying the AirSeal.

10 Why is that important? Because if there is  
11 wrongful conduct, you would need the sales of the AirSeal to  
12 go down and then those sales would have been picked up by  
13 Lexion.

14 Well, if we don't have the sales of AirSeal  
15 going down, there is no sales to be picked up by Lexion. So  
16 that starts to break the link between the alleged wrongful  
17 conduct and a claim of damages that Lexion put forth through  
18 Mr. Andrien.

19 Q. Mr. Splanski, can you please pull up slide 14.

20 Dr. Ugone, is there any other reason why you  
21 conclude that Mr. Andrien has not established an economic  
22 causal connection?

23 A. Well, there's a couple of things. That in the  
24 instructions for use, we've been hearing here at trial about  
25 the issue of air entrainment, about what is in the

Ugone - direct

1 instructions for use.

2 I know there has been some testimony about  
3 whether the doctors actually read the instructions for use,  
4 but we've also seen testimony about the whole sales process  
5 and how hospitals decide whether they're going to buy a  
6 medical device or not, and there's a fairly big process  
7 where if there was a problem or if there was something in  
8 the instruction for use, it's likely that that would have  
9 been -- have come up and been known.

10 Q. Is there anything else that you considered with  
11 respect to whether there was an economic causal connection?

12 A. Well, yes. There were a number of different things  
13 that I looked at. I mean, there's one slide I've got --  
14 this is jumping ahead a little bit -- where we've heard some  
15 testimony from a number of doctors. If we could put that  
16 up.

17 Q. I believe that's the next slide, please. Is this what  
18 you were referring to?

19 A. Well, what I was going to do was to go to the slide  
20 that has the checkmarks. I know I jumped ahead of you a  
21 little bit there, but go two or three slides.

22 All right. I can just speak if you can't find  
23 that slide.

24 Q. It's actually slide 8. Thank you. We skipped over  
25 it.



Ugone - direct

:51:05 1 A. I'm sorry.

:51:05 2 Q. Yes. There you go.

:51:07 3 A. Well, I put this slide together, and I thought it was  
:51:10 4 really important because we heard from Dr. David Lee, we  
:51:13 5 heard from Dr. Pedro Ramirez and Dr. David Earle, and they  
:51:21 6 talked about the reason why they liked the AirSeal. And  
:51:22 7 this is what we've heard all along, both from the brochures,  
:51:25 8 from the testimony of corporate representatives, from  
:51:30 9 SurgiQuest, that Dr. Doctor David Lee mentioned the stable  
:51:37 10 pneumo and the valveless access. How Dr. Ramirez mentioned  
:51:44 11 the stable pneumo and smoke removal. And Dr. Earle  
:51:48 12 mentioned the stable pneumo and valveless access.

:51:50 13 But the point was, this is why they liked  
:51:52 14 the AirSeal. They didn't mention the heat and  
:51:55 15 humidification, and I know part of the alleged allegations  
:51:58 16 in this case deal with heat and humidification. And they  
:52:01 17 basically said, you know, even if that had been known to us,  
:52:06 18 there's other reasons why we're buying the product. We  
:52:08 19 wouldn't have stopped buying the product. So, again, that  
:52:11 20 breaks the causal link.

:52:13 21 Q. Now turning to Lexion's Insuflow and Synergy, is it  
:52:20 22 your opinion there was a lack of demand for the perceived  
:52:23 23 benefits provided by Insuflow and Synergy?

:52:26 24 A. Well, yes. And if you think about it, there's the  
:52:31 25 discussion we've heard about heat and humidification, and

Ugone - direct

1 that there's no clear consensus in the medical community.

2 That's my understanding. I'm not a doctor, so I'm just

3 reporting, you know, the research that I've done. But

4 there's no clear consensus that that is a benefit. So it

5 was not something that caused purchases of the AirSeal or

6 the absence of that we've seen would have caused people to

7 stop buying the AirSeal.

8 Q. Mr. Splanski, can you please pull up slide 15.

9 Dr. Ugone, can you please walk the jury through  
10 what's contained on this slide.

11 A. Right. So the lack of demand for Lexion's Insuflo  
12 and Synergy, you can start at the left, benefits.

13 So there was the lack of perceived benefits  
14 provided by heated and humidified gas. That's what I  
15 have already talked about, when you've heard about that at  
16 trial.

17 So the question is, you know, if that's one of  
18 the attributes of the Lexion products, it's not clear that  
19 that is a demand driver on the part of consumers for the  
20 product.

21 The second point -- so we've got three buckets  
22 over here -- is that there's a lot of evidence, and I think  
23 we've even heard some of it in the deposition tapes right  
24 before I got on the stand, that there really isn't the sort  
25 of cost-benefit, which is, what's the cost of using the

Ugone - direct

:53:54 1 device versus the benefit you get out of using the device.  
:53:58 2 And a lot of hospitals just didn't think that cost-benefit  
:54:04 3 calculus was there for using the Lexion products.

:54:09 4 And then the third thing, and this really goes  
:54:11 5 to the causal, too, is even if -- remember what I said, a  
:54:16 6 couple of things have to happen. In the absence of the  
:54:18 7 wrongful conduct, the alleged wrongful conduct, the AirSeal  
:54:23 8 sales would have had to have gone down, but then they would  
:54:25 9 have had to have been picked up by Lexion.

:54:29 10 But there's a lot of stiff competition out there  
:54:32 11 for alternative products, and so that needs to be factored  
:54:35 12 into the damage analysis. And so when you take everything  
:54:38 13 I've been saying and looking at it at a high level from the  
:54:41 14 benefits, the cost-benefit and the competition, that breaks  
:54:45 15 that link to the damages that Lexion is claiming in this  
:54:50 16 case.

:54:51 17 Q. Mr. Splansky, can you please pull up slide 16.

:54:54 18 Now, Dr. Ugone, you mentioned that there was  
:54:56 19 some testimony at trial about the lack of perceived benefits  
:54:59 20 of dehumidification. Is what's contained on slide 16 what  
:55:03 21 you were referring to?

:55:04 22 A. Yes. So, for example, there's the testimony of Dr.  
:55:11 23 Kobza and then also Dr. Redan. You will remember when Dr.  
:55:16 24 Redan was testifying in person, he was providing his  
:55:21 25 insights and was critical about some aspects of what is

Ugone - direct

:55:27 1 going on here, but when asked, what were his colleagues  
:55:33 2 doing, my recollection is he had talked to his colleagues,  
:55:38 3 and they didn't care and they just continued to buy the  
:55:41 4 AirSeal.

:55:41 5 Q. Now, you also mentioned that a cost-benefit analysis  
:55:46 6 suggests that doctors than would be interested in purchasing  
:55:54 7 Insuflow or Synergy; is that correct?

:55:56 8 A. Yes.

:55:57 9 Q. What are the bases for your opinion?

:55:59 10 A. Well, I have a slide here that kind of just shows  
:56:02 11 side by side some of the dollar costs associated with the  
:56:07 12 two sets of products. And so on the left-hand side we have  
:56:11 13 the SurgiQuest AirSeal. On the right-hand side we have  
:56:16 14 Lexion, but we've got some additional components that I will  
:56:19 15 get to.

:56:20 16 But I think the jury will recall from prior  
:56:23 17 testimony that the AirSeal is about \$30,000. There's tubing  
:56:28 18 that's about \$80. The access port, which is another \$80.  
:56:32 19 And then if you look on the right-hand side, if you are  
:56:35 20 going to use the Insuflow or Synergy products, that is  
:56:40 21 substantially cheaper. You would use a different  
:56:42 22 insufflator than you use the Insuflow or the Synergy.

:56:46 23 The point is, that's much less expensive, or  
:56:49 24 that's, yes, less expensive than the AirSeal. And the point  
:56:52 25 is, as we've heard, the hospitals kind of do a cost-benefit.

Ugone - direct

1 How much do they have to pay and what are the benefits  
2 they're getting.

3 And in the case of where the AirSeal was  
4 purchased, even though it's more expensive than the Lexion  
5 option, the hospitals in terms of its cost-benefit analysis  
6 of what was making sense were going to the AirSeal side.

7 Q. Now, another bucket that you mentioned was  
8 competition.

9 Mr. Splanski, can you please go to the next  
10 slide.

11 Did Lexion face competition from alternative  
12 products on the market?

13 A. Yes. And so there's companies that produce market and  
14 sell insufflation tubing, insufflators, access ports,  
15 warming blankets. And, again, the thing you have to think  
16 about here is, when we're talking about damages and the  
17 causal link, the first thing we've established is that the  
18 doctors would not have stopped purchasing the AirSeal in the  
19 magnitudes that Mr. Andrien has put forth, and then even if  
20 somehow you would accept that assumption he made, he's  
21 basically saying of the robotics surgeries, 95 percent of  
22 those sales, if AirSeal didn't make them, would have gone to  
23 Lexion. But he did not incorporate into his analysis all of  
24 the alternative products that hospitals have a choice of.  
25 And so that's another flaw in his analysis.

Ugone - direct

1 Q. Okay. So let's just sum this up for the jury, if we  
2 can.

3 What is your opinion concerning whether  
4 Mr. Andrien proved an economic causal connection?

5 A. Well, Mr. Andrien had substantial damages known,  
6 22.1 million, and he basically took all of the AirSeal sales  
7 away from SurgiQuest and of the robotic component, which is  
8 80 percent, he then gave 95 percent of those sales to  
9 Lexion. And my point is, he has not demonstrated or proved  
10 that magnitude of the transferring from sales from AirSeal  
11 over to Lexion for all the reasons I said.

12 Q. Now let's turn to your opinion of Mr. Andrien's  
13 calculation of lost profits?

14 THE COURT: I think it's a good time to take our  
15 lunch break. We'll see you back at 2:00 o'clock.

16 (The jury was excused for a luncheon recess.)

17 THE COURT: Doctor, you're excused. Go get a  
18 bite to eat.

19 So where are we with the jury instructions?

20 MR. RYAN: We were going to meet.

21 THE COURT: I said we were going to discuss this  
22 at lunch. Right? Is there a report of any kind?

23 MR. RYAN: Your Honor, I misunderstood. I  
24 thought we were going to discuss these at lunch.

25 THE COURT: You were going to discuss them.

Ugone - direct

:00:04 1 MR. RYAN: Yes. I'm sorry.

:00:05 2 THE COURT: No. I misperceived that. All

:00:09 3 right. So let's come back at 2:00.

:00:10 4 MR. RYAN: Thank you, Your Honor.

:00:17 5 MR. WILLE: Thank you, Your Honor.

:00:18 6 (Luncheon recess taken.)

:00:18 7 - - -

:56:12 8 Afternoon Session, 1:58 p.m.

:58:21 9 THE COURT: All right. While Mr. Buckson gets

:58:22 10 the jury, what developments do you have to report?

:58:24 11 MR. RYAN: We actually have made significant

:58:26 12 progress, your Honor, during the break. So we would like,

:58:29 13 if we could during the next break, just to finish our

:58:32 14 discussion.

:58:32 15 THE COURT: Okay.

:58:33 16 MR. RYAN: We've actually gone through two or

:58:35 17 three of the most thorniest issues and we've come to

:58:37 18 resolution on those. We're optimistic we can work through

:58:42 19 the balance. Thank you, Your Honor.

:58:43 20 THE COURT: All right. We'll talk again at the

:58:45 21 break.

:58:45 22 MR. WILLE: Thank you.

:58:45 23 THE COURT: Is there anything further?

:58:48 24 MR. WILLE: No. Mr. Reilly is actually handling

:58:50 25 it.

Ugone - direct

:58:50 1 THE COURT: Anything?

:58:51 2 MR. WILLE: Nothing further, Your Honor.

:58:52 3 THE COURT: Okay.

:58:53 4 MR. WILLE: Thank you.

:59:08 5 THE COURT: Doctor, please.

:59:46 6 (The jury entered the courtroom.)

:00:56 7 THE COURT: Please take your seats.

:00:59 8 MS. REINCKENS: May I continue?

:01:00 9 THE COURT: Yes.

:01:01 10 MS. REINCKENS: Thank you, your Honor.

:01:01 11 BY MS. REINCKENS:

:01:05 12 Q. Dr. Ugone, before we broke, you were talking about

:01:07 13 your opinion of lack of economic causal connection with

:01:11 14 Mr. Andrien's lost profits. I would like to turn now

:01:14 15 to your opinion on Mr. Andrien's calculation of lost

:01:17 16 profits.

:01:20 17 And actually, I will have Mr. Splanski -- can

:01:26 18 you please pull up slide 73.

:01:29 19 Par Dr. Ugone, do you agree with Mr. Andrien's

:01:32 20 lost profits calculations?

:01:33 21 A. No, I don't. There's certain assumptions he makes in

:01:37 22 doing his calculation of claimed lost profits, and I've got

:01:42 23 some observations concerning his assumptions with respect to

:01:46 24 lost sales, and then also some assumptions that he makes

:01:51 25 with respect to cost, which ultimately deal with the



Ugone - direct

1     profitability of those lost sales. So I have some  
2     observations that I'd like to provide to the jury with those  
3     assumptions Mr. Andrien makes.

4     Q.     And can you explain in a little more detail what those  
5     unsupported assumptions are?

6     A.     All right. So essentially, if you recall, what  
7     Mr. Andrien did was he took all of AirSeal's sales, then  
8     took an 80 percent figure of that, and he said that's what  
9     would be in robotic surgery.

10           And he then said 95 percent of that  
11     80 percent that would be in robotics, so he's really taking  
12     95 percent of that 100 percent, he's saying would have gone  
13     to Lexion in the absence of the alleged wrongful conduct.  
14     And I'm going to show how that is an unreasonable number.  
15     But it basically is saying for every sale that he claims  
16     AirSeal would not have made, that there would have been a  
17     replacement sale by Lexion. So that's that 95 percent  
18     conversion rate that he uses.

19     Q.     So focusing in on that 95 percent conversion rate,  
20     what are your opinions regarding this?

21     A.     Well, remember what I said. In order to have this  
22     causal link to damages, if you think about it, there has to  
23     be some alleged wrongful conduct, and it has to be that if  
24     you take that away, AirSeal would have lost all of those  
25     sales. But as we've seen in the economic evidence, that

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1 hospitals and doctors are buying the AirSeal for three key  
2 benefits that have nothing to do with the heat and  
3 humidification assumption with respect to the alleged  
4 misrepresentations that Mr. Andrien is assuming.

5 So there's a break right there. He's saying  
6 they would have lost all of those sales when, in fact, we've  
7 seen all the evidence that doctors and hospitals are buying  
8 the AirSeal for other reasons. So those sales would not  
9 have gone away from SurgiQuest. But then he takes those,  
10 reduces them by 20 percent, and he looks at 80 percent of  
11 them and says, 95 percent of that remainder would have gone  
12 to Lexion. And that's problematic, because we also saw a  
13 lot of testimony that there's a debate and a real question  
14 over the benefits associated with heat and humidification.

15 So the first problem is, there wouldn't have  
16 been the reduction in AirSeal's sales that Mr. Andrien is  
17 assuming, and then there would not have been the bump up in  
18 Lexion's sales that he's assuming. And I'm going to show  
19 you some charts as to just how unreasonable his assumptions  
20 are.

21 Q. And before we get to the chart, do you have any  
22 opinion about Mr. Andrien's focus on robotic assisted  
23 surgeries?

24 A. Yes. He assumed that, but he did not provide me  
25 evidence that that was the focus of Lexion's sales for the

Ugone - direct

:05:06 1 Insuflow and the Synergy.

:05:08 2 Q. And does Mr. Andrien assume that AirSeal and Lexion's  
:05:12 3 Insuflow are the only two products used in an Intuitive  
:05:18 4 Surgical training center?

:05:19 5 A. Yes. He did say that, but we also heard testimony  
:05:21 6 from SurgiQuest personnel that they've never seen the Lexion  
:05:25 7 products in the Intuitive training facilities.

:05:28 8 Q. Can you please explain the significance of this  
:05:32 9 assumption in Mr. Andrien's damages calculation?

:05:34 10 A. Well, that's his result. That's how he gets to that  
:05:37 11 \$22 million figure. He has not talked about the costs on  
:05:40 12 the profit side, but that's how he gets to such a high, in a  
:05:43 13 sense, revenue number that he starts with from which he then  
:05:46 14 figures out the profits. He has to do that. But that  
:05:49 15 number is so high because he's assuming this one-to-one  
:05:53 16 relationship, he's essentially assuming there would have  
:05:56 17 been one less AirSeal sale for each misrepresentation, and  
:06:01 18 that would have been replaced by a Lexion sale.

:06:04 19 Q. Mr. Splanski, can you please pull up slide 24.

:06:07 20 Now, Dr. Ugone, you mentioned that you prepared  
:06:10 21 a chart. Is this the chart that you were referring to?

:06:12 22 A. Yes.

:06:13 23 Q. Can you please explain what is contained in this chart  
:06:17 24 to the jury?

:06:17 25 A. Sure. And I've been fumbling. I don't think I can

Ugone - direct

:06:23 1 get this laser to work. But --

:06:25 2 Q. I think you have to press the green button or what's  
:06:29 3 left of a green tag.

:06:30 4 A. Oh, okay. Let's see what happens. There we go.

:06:33 5 Okay. Very good. Thank you.

:06:34 6 Now, let me explain what this chart is so  
:06:39 7 there's no confusion. This chart is not the level of sales,  
:06:44 8 it's not how much sales Lexion is making. What this is, is  
:06:50 9 the rate of growth or the change, percentage change in  
:06:54 10 sales. So it's kind of like you may make a hundred dollars  
:06:57 11 a week, and then you get a five percent raise and make \$105.  
:07:03 12 This isn't showing \$100 and \$105. This is showing that five  
:07:08 13 percent. So each year, what is the percentage change or  
:07:13 14 increase or decrease in Lexion sales? That's what this is  
:07:16 15 showing.

:07:17 16 So if I may, when we look down here, it's hard  
:07:21 17 to see that, but that's 2004. And the beginning of the  
:07:26 18 claimed damage period is right here, and that's 2012, but  
:07:32 19 the first amount of claimed damages starts in 2013.

:07:40 20 So what I want to point out is, how is Lexion  
:07:44 21 growing from year to year before there's any alleged  
:07:47 22 wrongful conduct? And as you can see, the growth --  
:07:51 23 remember, this is the percentage change. The growth is  
:07:54 24 declining pretty much every year and goes from a high level  
:07:59 25 to a low level. But the real thing I want to point out is,

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1 in the year where damages are first being calculated, in the  
2 actual world, the growth of Lexion had gone all the way down  
3 to zero, and in the un-impacted years, before the alleged  
4 wrongful conduct, it was at a very low level. But because  
5 of those aggressive assumptions that Mr. Andrien has made,  
6 remember what I said. He's assuming all of those AirSeal  
7 sales would be lost, and he basically, in a robotic segment,  
8 95 percent was over Lexion.

9 Suddenly, if you look at his world that  
10 he's recreating, you get a 30 percent, if you go over the  
11 side here, a 30 percent increase in sales is what he's  
12 saying would have happened in the absence of wrongful  
13 conduct, when if you look at it in the real world, they have  
14 a zero percent increase. And if you look at it in the  
15 un-impacted years, it's at a very low rate, and he has it  
16 shoot up 30 percent.

17 Now, in fact, in the real world, the sales --  
18 the growth rate turned negative. What that means is sales  
19 actually started going down, but he still has the growth  
20 rate possible. And these positive amounts, if we just  
21 look at these un-impacted years from 2009 to 2012, he has  
22 got the increase in sales to be above even the un-impacted  
23 years.

24 So I know by looking at this that he's way  
25 overestimating claim damages. I'm going to show you another

Ugone - direct

:09:46 1 chart, but this is just one way to show that.

:10:33 2 Q. Now, Mr. Splansky, can you please pull up Slide 25.

:10:41 3 Is it also your opinion, Dr. Ugone, that Mr.  
:10:46 4 Andrien has understated Lexion's incremental calculation?

:10:50 5 A. Yes. I probably need to explain what incremental cost  
:10:53 6 is.

:10:53 7 Q. I was about to ask you to do that. Thank you.

:10:56 8 A. Think about it this way. When you make additional  
:10:59 9 sales, you are going to incur additional costs. You are  
:11:03 10 going to be putting your product together. So there might  
:11:06 11 be plastic or tubing that you have to buy. All of that goes  
:11:09 12 into the cost of goods sold.

:11:11 13 But there is additional costs to make additional  
:11:14 14 sales. You can't just have those sales materialize.  
:11:18 15 Somebody has got to go out on the marketplace and approach  
:11:23 16 customers and get them to buy the product. And so I have a  
:11:28 17 lot of issues with the additional costs that Mr. Andrien  
:11:35 18 uses to support those additional sales. But the main one I  
:11:39 19 want to focus on is this sales force one.

:11:43 20 Essentially -- can we maybe go to the next  
:11:48 21 chart.

:11:48 22 Q. Mr. Splansky, can you please pull up 26.

:11:52 23 A. Let me explain this chart and then I will explain the  
:11:56 24 problem with Mr. Andrien's assumption about the sales force.

:12:00 25 So in 2013, this is actual sales, as we can see

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1 down here. Maybe what I can do is describe that we have  
2 four panels here. We have a 2013 panel, a 2014 panel, a  
3 2015 panel, and a 2016 panel.

4 The green bar are the actual sales. The red bar  
5 is the increase that Mr. Andrien projects in his damage  
6 model. So in 2013, he is projecting that sales would have  
7 been 31 percent higher than actual. In 2014 he is  
8 projecting that sales would have been 53 percent higher than  
9 actual. In 2015 the sales would have been 81 percent higher  
10 than actual. And by the time you get to 2016, he is  
11 projecting sales will be 125 percent higher than actual.

12 What is the point I want to make? I am not  
13 quite sure if Mr. Andrien said this at trial or not, but you  
14 can imagine that if you are going to make 31 percent, then  
15 53 percent, then 81 percent, and 125 percent more sales, you  
16 are going to need more salesmen or salespeople. And, in  
17 fact, Mr. Andrien, in 2013, does not increase the number of  
18 salespeople.

19 So he is underestimating costs, because when you  
20 have a salesman you have got to pay their salary and pay a  
21 commission .

22 In 2014, no new salespeople. In 2015, no new  
23 salespeople.

24 Again, each of those years he is way  
25 underestimating costs.

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:13:56 1 Finally in 2016, he allows in his model for  
:14:00 2 some additional salespeople. So I disagree with the  
:14:03 3 calculations that he did, but at least he is bringing more  
:14:06 4 salespeople onto the force to make these sales.

:14:09 5 But the biggest problem I have with this model  
:14:12 6 is, no new salespeople in 2013, '14, '15, he finally brings  
:14:18 7 in new salespeople in 2016, but he underestimates the costs  
:14:24 8 associated with that.

:14:25 9 Those are my biggest criticisms of what he is  
:14:28 10 doing on the cost side. So he is way underestimating cost,  
:14:33 11 which means he is way overestimating the lost profits.

:14:36 12 Q. Were there also additional marketing and selling  
:14:45 13 expenses that would have been incurred by Lexion?

:14:48 14 A. Yes. I think we have got a slide here where we can  
:14:51 15 show that.

:14:54 16 Q. Was this the slide we were just looking at, I believe?

:14:58 17 A. Let me tell you which one it is here. Slide 25.

:15:02 18 Q. Thank you.

:15:08 19 A. What I have talked about so far is the sales force.

:15:11 20 But he is having, by 2016, 125 percent increase in sales.

:15:17 21 But he is assuming that they don't need any more back-office  
:15:22 22 people, what you call the general and administrative  
:15:24 23 expenses, no more legal people or accountants to help run  
:15:33 24 the infrastructure of the company.

:15:35 25 But he is also only just looking at what's



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1 called cost of goods sold. Let's say the materials to make  
2 the product, and some additional commissions in those first  
3 three years. And in no year does he take into account  
4 additional pamphlets, brochures, or advertising or travel.  
5 Whatever is required to make those additional sales. He  
6 doesn't, I guess the problem is, he doesn't reconstruct the  
7 company.

8 In other words, if you are going to have double  
9 the size of the company, there has got to be infrastructure  
10 to go along with that. There is additional cost. It's not  
11 just commissions for salespeople. He doesn't reconstruct  
12 the company to this larger size.

13 Q. What impact would these additional costs have on the  
14 lost profits number?

15 A. So by not including everything I have said, that makes  
16 the lost profits number, the claimed lost profits number,  
17 much higher.

18 And I realize I might have been touching the  
19 screen, so I will try to clear it.

20 Q. Doctor, have you reached an independent evaluation of  
21 lost profits damages?

22 A. I have.

23 Q. Can you please explain your independent evaluation to  
24 the jury?

25 A. Yes. I think it might be easiest, frankly, if we go

Ugone - direct

1 to Slide 27.

2 I looked at Mr. Andrien's work in its most  
3 simple explanation, I really just made two changes. The two  
4 changes have to do with the white lines here. One is the  
5 adjusted conversion rate, and the other is the incremental  
6 profit margin.

7 Essentially, the adjusted conversion rate is  
8 saying, let me look at how the Insuflo and the Synergy did  
9 in the market rather than two laparoscopic surgeries.

10 That was about a six-percent figure, about six  
11 percent of the surgeries. In the best year that Lexion ever  
12 had, six percent used Lexion products.

13 What I said was, okay, even if we get over this  
14 hurdle that all those AirSeal sales would not have been lost  
15 to SurgiQuest, let's just give them that. If those were  
16 going to be reallocated, let's reallocate those based on  
17 Lexion's market share in their best year ever, which was  
18 about 6 percent. Instead of giving them the 80 percent and  
19 95 percent of the 80 percent that Mr. Andrien did, I said,  
20 let's just give them their market share. That's six  
21 percent.

22 Then I allowed for additional salespeople in  
23 each of those years, 2013, '14, '15 and '16. So in all the  
24 years, not just in the last year. And I also allowed for  
25 other incremental expenses, like advertising or brochures

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1 and those types of things.

2 That brought the profit margin down to about 43  
3 percent. In many of the years Mr. Andrien had, in the first  
4 three years, had a profit margin of about 75 percent. But  
5 if you allow for the additional salespeople, the additional  
6 costs, the overall weighted average number is about 43  
7 percent.

8 If you make all of those changes, or actually I  
9 should say, if you just make those two changes, the 22.1  
10 million dollar figure of Mr. Andrien is reduced to  
11 1,170,055. And that's what my opinion is as to claimed  
12 damages, if the jury finds that wrongful conduct has taken  
13 place.

14 Q. Mr. Splansky, can you please go to Slide 28. Dr.  
15 Ugone, do you have a further opinion based on alternative  
16 potential liability findings?

17 A. Yes. My understanding of what is in dispute here  
18 revolves around a heated and humidification claim, an air  
19 entrainment claim, a smoke filtration claim.

20 What I am trying to do here is say, there could  
21 be different or alternative liability findings by the jury.  
22 You could find that there is either misrepresentations or  
23 wrongful conduct with respect to all three, or with two, or  
24 with only one. And there is three different options on the  
25 one.

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:20:38 1 So the guidance I am giving here is, whenever  
:20:41 2 there is a heating and humidification claim, you can see  
:20:45 3 what I am doing with the laser pointer, that would give you  
:20:48 4 the 1.2 million dollars in claimed damages, if liability is  
:20:53 5 found with respect to what's on each of those lines, which  
:20:58 6 might have all three claims, only heating and  
:21:03 7 humidification, or two out of the three but including  
:21:08 8 heating and humidification.

:21:09 9 If the jury were to only find for air  
:21:12 10 entrainment, or were only to find for smoke filtration, or  
:21:16 11 were to find only for air entrainment and smoke filtration,  
:21:23 12 damages would have to be zero because the InsufLOW and the  
:21:28 13 Synergy, as I understand it, don't provide those  
:21:30 14 capabilities.

:21:31 15 So there couldn't have been lost sales, even if  
:21:34 16 you find liability. So there wouldn't be any lost profits  
:21:38 17 damages.

:21:38 18 Q. I would like to break that down just a little bit more  
:21:41 19 for the jury. Can you please explain why you have the  
:21:44 20 number zero next to air entrainment only?

:21:47 21 A. Because even if the jury were to find that wrongful  
:21:51 22 conduct had taken place or that there was a  
:21:54 23 misrepresentation with respect to the air entrainment issue,  
:22:00 24 my understanding is that Lexion is putting forth the  
:22:03 25 InsufLOW product and the Synergy product, and my

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:22:06 1 understanding is those products do not solve this problem.

:22:11 2 Q. How about for smoke filtration, why is it that you

:22:15 3 have a zero there?

:22:16 4 A. Exact same issue, that if the jury were to find that

:22:21 5 there was either a misrepresentation or some false

:22:23 6 dissemination in the marketplace relating to smoke

:22:27 7 filtration and the AirSeal, if that's the only claim you

:22:32 8 were to find liability on, the InsufLOW and the Synergy

:22:37 9 don't provide smoke filtration capabilities. So there

:22:41 10 wouldn't have been any lost sales. So that's why that

:22:44 11 number would be zero.

:22:45 12 Q. Is it your understanding that Mr. Andrien is offering

:22:50 13 no opinion on lost profits for lost sales of Lexion's smoke

:22:58 14 removal devices?

:22:58 15 A. That's correct. He has only presented his

:23:03 16 calculations with respect to the InsufLOW and Synergy

:23:05 17 products.

:23:05 18 Q. Did Mr. Andrien attempt to distinguish his lost

:23:08 19 profits calculations based on the type of claim at issue?

:23:14 20 A. I might need a little help with your question. But I

:23:18 21 think I understand what you want. He gave one number, the

:23:21 22 22.1 million dollars. He didn't break it out like I have on

:23:25 23 the board here.

:23:26 24 Q. Do you agree with that approach?

:23:27 25 A. No, because there is a number of different outcomes

Ugone - direct

1 that could happen. We don't know in advance how the jury  
2 may rule. So he hasn't given the jury any options if any of  
3 these different possibilities were to be found by the jury.

Q. Mr. Splansky, can you please pull up Slide 29.

Actually, go to 36.

Mr. Ugone, do you have an opinion as to Mr.  
Andrien's corrective advertising related damages?

If we can go back to 29. Back to my question:  
Do you have an opinion as to Mr. Andrien's corrective  
advertising related damages?

A. I do.

Q. Can you please summarize your opinion for the jury?

A. Mr. Andrien testified to the jury that corrective  
advertising damages should be 18.7 million dollars. It is  
my opinion that that is a significantly overstated number.

Q. If we can go to the next slide, please, Mr. Splansky.

Here this slide lists some flawed assumptions in  
Mr. Andrien's calculation of corrective advertising damages.  
Can you please explain these to the jury, Dr. Ugone?

A. Right. There is a couple of things I think I will  
want to point out, is that, if you recall, Mr. Andrien  
basically assumed that the only way to do the corrective  
advertising is this face-to-face meeting between the  
salespeople and doctors, instead of trying to figure out the  
efficient way of having corrective advertising, and the most

Ugone - direct

1 appropriate cost way, it's almost like he came up with the  
2 most expensive way. And that's because he is assuming  
3 face-to-face meetings, or at least that's what I take his  
4 calculations to be, assuming face-to-face meetings between  
5 salespeople and doctors.

6 That is one item.

7 He is also assuming that, you see in the middle  
8 column, that all the SurgiQuest sales were made because of  
9 the alleged false statements. And we know that that isn't  
10 true. We have seen a lot of testimony and there have been  
11 three doctors that have testified for SurgiQuest saying why  
12 they bought the AirSeal. And it had nothing to do with the  
13 heat and humidification aspect, and they said they would  
14 have continued to buy the AirSeal even if they had known  
15 that.

16 And we can continue to see what's up here. It's  
17 all along those lines.

18 And he is assuming that all of the alleged  
19 misrepresentation caused Lexion damages. And we know that's  
20 not true, because their products don't even provide some of  
21 the capabilities that there has allegedly been some  
22 misrepresentations on.

23 And he also didn't divide his number, he failed  
24 to opine on which allegations of false advertising caused  
25 the lost sales.

Ugone - direct

:26:44 1 So there is some additional comments I have to  
:26:46 2 make. But on a conceptual basis, that is kind of the  
:26:50 3 problems with what Dr. Andrien did.

:25:02 4 Q. Mr. Splanski, can you please go to the next slide.

:26:12 5 Are there other flawed assumptions, Dr. Ugone,  
:26:18 6 that you considered with respect to Mr. Andrien's corrective  
:26:20 7 advertising damages?

:26:21 8 A. Right. And I think what struck me was that a number  
:26:29 9 of surgeons or hospitals were aware already of the allegedly  
:26:37 10 correct information versus what the misrepresentation  
:26:41 11 are.

:26:41 12 And if we just take the very simple case of  
:26:43 13 Dr. Redan, in his own hospital, at Florida Hospital  
:26:50 14 Celebration Health, he tried to, I guess, describe to his  
:26:55 15 colleagues what the alleged misrepresentations are to his  
:26:58 16 colleagues. Basically said, we're just going to stay doing  
:27:02 17 what we're doing. And so it's not like there has to be any  
:27:04 18 correction there. And, in fact, they were, you know, using  
:27:08 19 AirSeal products, and a lot of other hospitals were using  
:27:11 20 AirSeal products even with the knowledge of what Lexion is  
:27:16 21 claiming to be the misrepresentations.

:27:19 22 Q. Mr. Splanski, can you please go to the next slide.

:27:22 23 And is what is contained here on this slide  
:27:27 24 another example of such an assumption?

:27:30 25 A. Right, because here we already have that these two



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1 hospitals, Memorial Sloan Kettering Cancer Center and Aurora  
2 Medical Center in Grafton, Wisconsin, were already informed  
3 by Lexicon, or Lexion, and they continued to purchase the  
4 AirSeal. So it's not like it would have to be corrective  
5 advertising for these hospitals. So he did a very  
6 mechanical calculation, not taking into account or not  
7 calculating what would have to be corrected and what would  
8 not have to be corrected, or even if he took his old number  
9 and somehow proportionalized it down, taking into account  
10 those customers, where there would not have to be corrective  
11 advertising, he didn't do any of that. His calculation just  
12 maximized the number.

13 Q. Can you please go to the next slide, Mr. Splansky.

14 Dr. Ugone, are there other measures of  
15 corrective advertising that could have considered by  
16 Mr. Andrien?

17 A. Yes. And these were other methods of corrective  
18 advertising that Mr. Andrien did not consider. You know,  
19 one method is, you put a corrective statement on  
20 SurgiQuest's website. Another is if liability were to be  
21 found in this courtroom by the jury, there could be a  
22 distribution of that Court ruling to customers and potential  
23 customers, or there could be letters to the customers. And  
24 all of those, especially the distribution of a Court ruling,  
25 which would carry weight, I would think is a lot less

Ugone - direct

:29:09 1 expensive than using the approach of salespeople having to  
:29:14 2 go face to face.

:29:15 3 And you could put together an effective campaign  
:29:20 4 in a manner that's much less costly than the \$18.7 million  
:29:24 5 that Mr. Andrien is opining to.

:29:29 6 Q. Mr. Splanski, can you please go to the next slide.

:29:36 7 A. So this is kind of a summary.

:29:37 8 Q. Okay. Thank you.

:29:38 9 A. If I may.

:29:39 10 So he hasn't presented the least costly way of  
:29:43 11 making the correction. I thought it was interesting that he  
:29:46 12 did say that Lexion has incurred \$30,000 in corrective  
:29:51 13 advertising. There's a typo in that, so forgive that. But  
:29:56 14 he said that Lexion has incurred \$30,000 in corrective  
:29:59 15 advertising. To me, that seemed a little strange. They're  
:30:02 16 claiming \$22 million in lost profits, but they've only spent  
:30:07 17 \$30,000 to try to fix a perception in the marketplace. That  
:30:12 18 seemed low to me.

:30:14 19 He also presented this 25 percent rule, although  
:30:20 20 he wasn't really relying on it. But I think the thing to  
:30:23 21 keep in mind is that with the 25 percent rule, that's not  
:30:28 22 tied to the facts and circumstances of the case. That's not  
:30:31 23 tied to, you know, what's the best way to disseminate the  
:30:36 24 correct information if liability is found. It's just a  
:30:39 25 percentage. And so you really need to look at the facts and

Ugone - direct

1 circumstances of this case.

2 And then the other thing I noticed was that on  
3 their financial statements over three years I think it has,  
4 Lexion has printing and postage expenses of about \$37,000.  
5 I kind of said, okay. That's what they are doing in terms  
6 of printing, postage and advertising. So that would at  
7 least kind of give us a relevant range of what it might take  
8 if you were going to do some sort of physical mailing or,  
9 like you said, you could just put it on the website.

10 Q. Dr. Ugone, can you please briefly summarize your  
11 opinion as to whether Lexion is entitled to recover  
12 corrective advertising damages?

13 A. Well, ultimately, I think the jury is going to decide  
14 that. My guidance is that if a jury decides that corrective  
15 advertising damages is appropriate, hopefully, you can see  
16 that that \$18.7 million way overstates what the corrective  
17 advertising amount would be. And, in fact, I have tried to  
18 give you some relevant ranges, and I've tried giving you,  
19 help you understand some options. That would be the least  
20 costly way of providing that corrective advertising.

21 Q. Now turning to unjust enrichment damages, Dr. Ugone,  
22 have you reviewed Mr. Andrien's calculations of Lexion's  
23 unjust enrichment damages?

24 A. Yes, I have.

25 Q. And do you have an opinion regarding his analysis?

Ugone - direct

1 A. I do. Mr. Andrien opined to unjust enrichment of  
2 \$120 million. Now, what the jury needs to understand -- and  
3 again I'm giving you an economic perspective, I'm not giving  
4 you a legal perspective, that would come from others, but  
5 generally in disgorgement-type cases, the plaintiff gets the  
6 revenues and then the defense has to talk about some offsets  
7 to that.

8 So the answer is not the number that the  
9 plaintiffs put forth. So Mr. Andrien put forth 120 million,  
10 but it's in his report. And I think he even said at the  
11 trial, all he has to do is identify the revenues and then  
12 the defendants or the alleged wrong-doer has to subtract out  
13 the cost to try to figure out if there was any unjust  
14 enrichment. And so that's what I did, was look at the costs  
15 that are associated with SurgiQuest.

16 Q. Mr. Splanski, can you please pull up slide 36.

17 A. And one thing I looked at here was with SurgiQuest,  
18 I mean, essentially, the AirSeal is there. It's their  
19 primary product. And if you look over time, all I'm going  
20 to point out here is that with respect to a disgorgement  
21 remedy, it's almost like it doesn't work in this situation.

22 If you are trying to look at the old dot and  
23 games measured in terms of the process of SurgiQuest, and  
24 across the top we see various years and we see revenues,  
25 cost of goods sold, gross profit, operating expenses,

Ugone - direct

1 operating income, but if you get all the way down to the  
2 bottom of what's called the income statement, you will see  
3 that SurgiQuest was actually losing money every year. And  
4 so from a disgorgement point of view, if one wanted to  
5 disgorge the alleged ill-gotten gains, that remedy doesn't  
6 work in this situation because they were losing money. It  
7 wasn't like they were making money to disgorge.

8 So Mr. Andrien gets that top line, \$120 million  
9 of revenues associated with the AirSeal. He doesn't deduct  
10 the costs. But if you just look at the company, you see  
11 they were actually losing money over time. I think you  
12 heard testimony about this from Mr. Peters.

13 So in this sort of situation, this approach to  
14 coming up with disgorgement damages in a sense doesn't work  
15 because there isn't any money to disgorge. They were losing  
16 money.

17 Q. Okay. Now, finally, turning to SurgiQuest's request  
18 for an injunction, Dr. Ugone, have you also provided an  
19 opinion regarding SurgiQuest's request for an injunction  
20 against Lexion?

21 A. I have.

22 Q. Can you please briefly describe the nature of your  
23 opinion for the jury?

24 A. Sure. So from an economic perspective, I've reached  
25 the opinion that a permanent injunction as to the

Ugone - direct

1 dissemination of, for example, information related to the  
2 complications chart, a permanent injunction against the  
3 dissemination of that information would be warranted in this  
4 case.

5 Q. Mr. Splansky, can you please pull up slide 38.

6 Now, Dr. Ugone, in the chart that you were  
7 referring to, it's shown here on Exhibit 38; is that  
8 correct?

9 A. Right. I think the jury has seen it. So there it is,  
10 a document that has the chart attached to it.

11 Q. And how did you arrive at the conclusion that an  
12 injunction is warranted here?

13 A. Well, the way I thought about it was, and also based  
14 on how these assessments are made, and the question is:  
15 Would the dissemination of this information, if it were to  
16 continue going into the future, is it likely to have or  
17 create irreparable harm to SurgiQuest? And it's even beyond  
18 that. Not only is it likely to create irreparable harm,  
19 does it create a harm where you can't figure out a monetary  
20 remedy? In other words, if the false information then  
21 continued to be disseminated into the marketplace, it's not  
22 like SurgiQuest could just come back to Lexion and say, pay  
23 me a certain amount of money because I've been harmed by  
24 that.

25 Part of the problem is, you don't know who it's

Ugone - direct

going to be disseminated to. You don't know who did not buy because of this information, and so you would have, from my perspective, just an easier way of saying it is you would have a very hard time proving up how much you've been harmed from the dissemination of this information if the jury finds it to be false, and if Lexion continues to disseminate it, how would you ever do a damages calculation when you don't know where that has gone and who hasn't bought because of the information.

And it's precisely because of those reasons, irreparable harm and an inability to come up with a complete monetary remedy that leads me to say that, from an economic perspective, there should be a permanent injunction.

Q. And, finally, Mr. Splanski, can you please go to slide 45.

Dr. Ugone, was your opinion concerning an injunction based on the assumption that the underlying conduct was ongoing?

A. That's part of it. In other words, if Lexion said they wouldn't do this again, then from an economic perspective, you wouldn't need the permanent injunction. But there has been some testimony that the dissemination of this information, it is ongoing, and so that's why I'm giving my statements about the permanent injunction.

Q. Mr. Splanski, the last slide of the presentation,

Ugone - cross

1 please.

2 And, Dr. Ugone, is this the testimony that you  
3 were just referring to here?

4 A. Yes. And, in fact, we won't read the whole thing. If  
5 we go down to the very bottom, Patrick Spearman, who I  
6 believe is the CEO of Lexion said: I just mentioned it to a  
7 urologist two weeks ago about the subcutaneous emphysema  
8 issue. And so in my mind, that shows that it's ongoing and  
9 that's what's problematic.

10 MS. REINCKENS: Thank you, Dr. Ugone. No  
11 further questions.

12 THE COURT: All right. Mr. Wille?

13 MR. WILLE: Permission to a broach with binders,  
14 Your Honor?

15 THE COURT: Yes.

16 (Binders handed to the Court and to the  
17 witness.)

18 MR. WILLE: If it pleases the Court, Your Honor?

19 THE COURT: Yes, sir.

20 CROSS-EXAMINATION

21 BY MR. WILLE:

22 Q. Okay. Good afternoon, Dr. Ugone.

23 A. Good afternoon.

24 MR. WILLE: Please put up slide number 8,  
25 Mr. Barnes.



Ugone - cross

:39:52 1 BY MR. WILLE:

:39:52 2 Q. So slide number 8 is the drivers of purchase slide  
:39:57 3 that you presented in your direct testimony; is that  
:39:59 4 correct?

:39:59 5 A. Yes.

:39:59 6 Q. Okay. And there are three witnesses that are included  
:40:02 7 here; correct?

:40:02 8 A. That's correct.

:40:03 9 Q. All three of those witnesses are connected to  
:40:06 10 SurgiQuest; is that right?

:40:07 11 A. I would agree with that. My opinion wasn't based just  
:40:11 12 solely on this. This is one component, but I'm not going to  
:40:15 13 disagree with you that these are three expert witnesses  
:40:18 14 provided by SurgiQuest. But I also have other information  
:40:20 15 as well.

:40:21 16 Q. Okay. So Dr. Lee is a paid expert witness; is that  
:40:24 17 correct?

:40:24 18 A. I believe that to be true, sure.

:40:28 19 Q. Dr. Ramirez is a paid expert witness; is that correct?

:40:31 20 A. I mean, that's common in the industry, that when  
:40:33 21 you're an expert witness, that's your job, and so you  
:40:35 22 get compensated, so I'm not going to disagree with you.  
:40:38 23 Sure.

:40:38 24 Q. Right. And David Earle was on SurgiQuest's advisory  
:40:42 25 board and stock options of SurgiQuest; right?

Ugone - cross

:40:44 1 A. I think I would agree with you.

:40:46 2 Q. Okay. And you're aware Dr. Earle never read the  
:40:49 3 instructions for use for the product; is that right?

:40:51 4 A. I think I would agree with that, but there's a lot of  
:40:57 5 testimony that the doctors, any doctors, don't read the  
:40:59 6 instructions for use. It's not even clear to me that -- we  
:41:03 7 would have to check whether Mr. Redan read the instructions  
:41:05 8 for use. But I think we all know the sales process, and I  
:41:09 9 think what the doctors do is leave it up to the people  
:41:13 10 evaluating the product early on to go through the  
:41:16 11 instructions for use, decide that everything is okay, and so  
:41:19 12 that takes the burden off the --

:42:06 13 THE COURT: Doctor, we are tight for time. He  
:42:10 14 gets to direct the examination. Please respond, if you can.

:42:13 15 BY MR. WILLE:

:42:14 16 Q. Sir, it is true, Dr. Earle never read the instructions  
:42:16 17 for use. Right?

:42:17 18 A. I think that's true.

:42:18 19 Q. Dr. Ramirez didn't know about air entrainment prior to  
:42:21 20 getting hired in this case. Correct?

:42:23 21 A. I believe he testified to that, yes.

:42:24 22 Q. Dr. Lee never knew about air entrainment prior to  
:42:27 23 getting hired in this case. Right?

:42:29 24 A. Those are all accurate statements, I believe. But  
:42:32 25 they also said it wouldn't have changed their decision on

Ugone - cross

:42:34 1 the AirSeal.

:42:34 2 Q. And they were paid experts by SurgiQuest. Right?

:42:39 3 A. Well, they are expert witnesses and that was their  
:42:41 4 job.

:42:41 5 Q. You listened to the testimony of Dr. Ramirez. Right?

:42:44 6 A. Yes.

:42:44 7 Q. And you understood him to explain that his exposure to  
:42:49 8 the AirSeal system at a training laboratory was one of the  
:42:53 9 things that influenced him to purchase AirSeal. Right?

:42:57 10 A. I think I recall that, yes.

:42:59 11 Q. And you would agree that people using products in a  
:43:03 12 training laboratory can be influenced to purchase the  
:43:06 13 products after trying them out in the training laboratory as  
:43:10 14 Dr. Ramirez explained. Correct?

:43:12 15 A. I think that could happen. I wouldn't disagree.

:43:14 16 Q. That provides a potential competitive advantage to  
:43:18 17 those companies lucky enough to have their product to be one  
:43:22 18 of the ones doctors can try out in the training laboratory.  
:43:24 19 Right?

:43:25 20 A. I want to be a little careful. You said lucky enough.  
:43:28 21 Usually you have to demonstrate the capabilities to get that  
:43:31 22 opportunity. But if we take away lucky enough, that can be  
:43:37 23 something that happens to the sales prices.

:43:39 24 Q. Right. In your understanding Intuitive is not going  
:43:42 25 to invite someone into its laboratory if people haven't

Ugone - cross

:43:46 1 proven that their product is worthy of being put in that  
:43:49 2 laboratory. Right?

:43:52 3 A. I can't speak for Intuitive, but as an economist and  
:43:55 4 businessperson I would agree with you.

:43:57 5 Q. And you will agree that having the only product in  
:44:00 6 that training laboratory that can perform a particular  
:44:04 7 function would likely generate sales for the company if  
:44:07 8 there was demand for that feature. Right?

:44:13 9 A. I think it's a little more complicated than how you  
:44:17 10 are saying it. I think that could be a way of exposing  
:44:24 11 potential purchasers to a product, but there is a much more  
:44:28 12 detailed sales process and hurdles you have to get over. I  
:44:32 13 am not just disagreeing with you that there is this initial  
:44:34 14 exposure. But that doesn't guarantee a sale.

:44:37 15 Q. Okay. But you do agree that there is demand for  
:44:40 16 heating and humidification. Correct?

:44:42 17 A. Well, I guess the best I can say is that has not, the  
:44:48 18 way I have seen the evidence, it's not unambiguous.

:44:51 19 Q. If there were no demand, Lexion wouldn't sell any  
:44:55 20 products. Right?

:44:56 21 A. I guess what I was reacting to was the strength of the  
:45:01 22 statement you were saying. You were making it unambiguous  
:45:04 23 when my understanding of the testimony has been that there  
:45:08 24 is debate and in fact many doctors that don't see the  
:45:11 25 benefits of it.

Ugone - cross

:45:12 1 So you can't unambiguously say that there is  
:45:15 2 **benefits.**

:45:15 3 Q. But some people do believe there is benefits. Right?

:45:19 4 A. I am not going to disagree that there may be some  
:45:22 5 **people that see benefits.**

:45:24 6 Q. And to an economist, that's demand. Right?

:45:27 7 A. Yes. But it's always important to talk about is the  
:45:31 8 **demand here, is the demand here (indicating), is the demand**  
:45:33 9 **such that all of the sales of AirSeal would have gone over**  
:45:37 10 **to Lexion. I don't think that part has been shown.**

:45:40 11 Q. Can I have Slide No. 4, Mr. Barnes, please.

:45:45 12 So were you here when we played the deposition  
:45:47 13 **of Mr. Carlos Babini?**

:45:50 14 A. I think I am aware of his testimony.

:45:52 15 Q. So you are aware that Mr. Babini got customer feedback  
:45:56 16 **to create a set of preliminary customer requirements.**  
:46:00 17 **Right?**

:46:01 18 A. Can I read this real quick?

:46:03 19 Q. Yes.

:46:10 20 A. Yes, I remember this. I think I have it in my report,  
:46:13 21 **yes.**

:46:13 22 Q. So he indicated that it would be a nice feature to  
:46:17 23 **have for the 50 percent of the market that would want one.**  
:46:20 24 **Right?**

:46:21 25 A. I think there is counter-evidence. But I am not going

Ugone - cross

:46:23 1 to disagree with what he said. That was his testimony.

:46:25 2 Q. Intuitive Surgical is the company that makes the da

:46:29 3 Vinci robot. Right?

:46:30 4 A. Yes.

:46:30 5 Q. They have training laboratories where doctors go to

:46:34 6 train. Right?

:46:34 7 A. That is my understanding.

:46:35 8 Q. And Lexion was invited by Intuitive to supply the

:46:40 9 Insuflow for use at the Intuitive training facility.

:46:42 10 Correct?

:46:44 11 A. The best I can say is that there has been testimony

:46:47 12 where it hasn't been seen at the institutes. I think there

:46:52 13 is disagreement among the parties, because, I think, like

:46:58 14 you are saying, Lexion either says they are invited or I

:47:01 15 think they have even said where it was at the institutes,

:47:04 16 but then we have the other side where SurgiQuest says they

:47:08 17 have never seen the Lexion products.

:47:09 18 Q. If we believe Lexion's witnesses, in 2012 they were

:47:14 19 invited to Intuitive's laboratory. Right?

:47:16 20 A. Okay, sure.

:47:17 21 Q. Can I have Slide No. 6, Mr. Barnes.

:47:21 22 Ms. Amman explained how the product got into the

:47:25 23 training lab. Right?

:47:26 24 A. Yes. Do I need to read this?

:47:29 25 Q. You agree that Ms. Amman testified that Intuitive

Ugone - cross

:47:33 1 invited Lexion to put their products into the lab because  
:47:37 2 they had found that the products had helped with things like  
:47:40 3 lens fogging and visualization that occurred when using the  
:47:44 4 robot. Right?

:47:45 5 A. Yes. Just give me a second. I am reading the bottom  
:47:50 6 paragraph here.

:47:54 7 That was her testimony, sure.

:47:56 8 Q. There has also been testimony that after Lexion had  
:47:59 9 its product in the Intuitive lab for the da Vinci robot for  
:48:04 10 robotic surgery, that doctors would even contact Lexion  
:48:09 11 asking to buy the product without being approached by a  
:48:13 12 sales representative. Isn't that right?

:48:16 13 A. That happens, sure. But also there is also a sales  
:48:19 14 process. A doctor just doesn't call Lexion to buy a  
:48:23 15 product.

:48:23 16 Q. Were you here when Mr. Spearman testified?

:48:26 17 A. I am saying there is more to the process, is my  
:48:29 18 understanding. There has got to be certain approvals.

:48:32 19 Q. But you don't deny that doctors have contacted Lexion  
:48:35 20 after using Lexion's products at the Intuitive lab and asked  
:48:39 21 to purchase the product. Right?

:48:41 22 A. I think there has been that testimony.

:48:44 23 Q. In fact, didn't Ms. Amman testify that lots of sales  
:48:49 24 for Lexion are attributed to that product being in the  
:48:53 25 Intuitive lab?

Ugone - cross

:48:55 1 A. You would have to show me her testimony. I have a  
:48:59 2 tendency to look at it a little differently going into the  
:49:02 3 damages model. In other words, the support for this 95  
:49:07 4 percent claim. We have seen a 50 percent number. We have  
:49:10 5 seen some. We have seen, like what you are saying, some  
:49:14 6 doctors will call. The issue I have is that Mr. Andrien  
:49:17 7 used a 95 percent figure to replace the AirSeal.

:49:20 8 Q. I have Ms. Amman's testimony up on the screen here  
:49:24 9 from 709 to 710 of the trial transcript.

:49:30 10 "Once Lexion's product was in the Intuitive lab,  
:49:31 11 what effect did have on Lexion's sales?

:49:34 12 "Answer: A lot of sales were attributed to the  
:49:38 13 Intuitive Robotics lab. We were getting leads out of there,  
:49:40 14 and then surgeons would bring it into their hospital  
:49:50 15 specifically and start using it."

:49:52 16 Did I read it correctly?

:49:53 17 A. Yes. But what is noticeably absent is she didn't say  
:49:58 18 and we would replace the AirSeal 100 percent.

:50:00 19 Q. Later SurgiQuest's AirSeal started being used in the  
:50:03 20 Intuitive training facility. Right?

:50:05 21 A. Yes.

:50:05 22 Q. So if the jury finds that SurgiQuest was telling  
:50:08 23 customers that AirSeal did the same thing as Insuflow and  
:50:13 24 surgeons believed that, that would mean that there were two  
:50:16 25 choices for heating and humidification at the Intuitive



Ugone - cross

:50:19 1 laboratory rather than one. Correct?

:50:22 2 A. I think I am going to need your question again. Can

:50:26 3 you just ask it again and slow down a little bit?

:50:29 4 Q. If the jury finds that SurgiQuest was telling

:50:31 5 customers that AirSeal did essentially the same thing as

:50:34 6 Insuflow and surgeons believed that, that would mean that

:50:38 7 there were two choices for heating and humidification in the

:50:44 8 Intuitive laboratory rather than one. Correct?

:50:46 9 A. I am missing the part when you are saying that would

:50:49 10 mean there is two choices in the training lab. I am missing

:50:53 11 how that was happening.

:50:54 12 Q. Lexion was in the training lab. Right?

:50:56 13 A. Yes. Previously.

:50:58 14 Q. Along comes AirSeal.

:51:00 15 A. In your question, are you assuming they are

:51:02 16 overlapping or not?

:51:03 17 Q. Well, the allegations, you understand, are that

:51:10 18 SurgiQuest has told people their product is essentially the

:51:13 19 same as Insuflow. Right?

:51:15 20 A. Yes. I don't know I would quite characterize it that

:51:18 21 way. But I understand that's Lexion's position.

:51:20 22 Q. Before SurgiQuest comes along we have one product in

:51:23 23 the Intuitive lab that does heating and humidification.

:51:26 24 True?

:51:27 25 A. Accepting your assumptions, sure.

Ugone - cross

:51:28 1 Q. And then the AirSeal comes along, assuming they tell  
:51:32 2 people they heat and humidify and surgeons believed them,  
:51:35 3 now there is two choices in the Intuitive lab. Right?

:51:38 4 A. Let's just call it under your hypothetical, yes. But  
:51:43 5 still, that doesn't mean that 95 percent of the sales go to  
:51:46 6 Lexion.

:51:46 7 Q. Let's talk about that for a minute, because one of the  
:51:49 8 things that you say drives the purchase of these products is  
:51:55 9 stable pneumoperitoneum?

:51:56 10 A. Right.

:51:56 11 Q. The way you keep the abdomen inflated is getting a lot  
:52:00 12 of gas to flow into the abdomen. Right?

:52:02 13 A. I would accept that from a layman's point of view,  
:52:05 14 sure.

:52:05 15 Q. And you are aware that the Lexion Synergy trocar has  
:52:08 16 the highest flow of any conventional trocar on the market.  
:52:12 17 Correct?

:52:13 18 A. I do understand it has a high gas flow, yes.

:52:15 19 Q. So if a doctor in the robotics -- stable pneumo is  
:52:22 20 important for robotic surgery. Right?

:52:25 21 A. Yes.

:52:25 22 Q. If a doctor doing robotic surgery wanted stable  
:52:31 23 pneumoperitoneum and didn't want air in the abdomen, the  
:52:33 24 next best place to turn for a trocar that will have high  
:52:37 25 flow is the Lexion Synergy trocar. Isn't that right?

Ugone - cross

:52:42 1 A. You are making an assumption as to what would happen  
:52:44 2 as opposed to whether that is what would happen in the  
:52:48 3 marketplace. If that were true I think we would see a much  
:52:53 4 higher, what's called a penetration rate of the products  
:52:55 5 into the marketplace above six percent. We don't see that.  
:52:58 6 You are making the assumption that if you don't buy an  
:53:01 7 AirSeal you buy a Lexion product. That is not clear, given  
:53:06 8 the low market penetration rate of the Lexion products and  
:53:09 9 all the other competitors out there.

:53:10 10 Q. That could be as a result of the false advertising by  
:53:13 11 SurgiQuest. Correct?

:53:14 12 A. No. Because what you are saying is take away the  
:53:17 13 false advertising and they all would have gone to the Lexion  
:53:20 14 products. And I am saying, that is ignoring all the other  
:53:23 15 competition in the marketplace.

:53:23 16 Q. But if a doctor wanted to maintain stable  
:53:27 17 pneumoperitoneum, and didn't want air in the abdomen, the  
:53:30 18 best place to turn is the Lexion Synergy trocar. Right?

:53:35 19 A. That's an assumption that hasn't been proven. The way  
:53:38 20 I kind of think about it is -- I own a truck, a Silverado,  
:53:44 21 it's a two-door Silverado, and I could have bought a  
:53:47 22 two-door Ford.

:53:49 23 But if for some reason I didn't buy my two-door  
:53:53 24 Silverado, that doesn't mean just because the Ford had two  
:53:55 25 doors also that I would have bought the Ford. I might have

Ugone - cross

1 bought a four-door. I might have bought one of those with  
2 the third door.

3 There is all kinds of different options. You  
4 are making the assumption that the next best alternative is  
5 the Lexion product. But that hasn't been demonstrated or  
6 proved.

7 Q. Isn't it stable pneumoperitoneum, sir, that you  
8 contend drives sales of the AirSeal product?

9 A. You have to be careful. I said three key benefits.  
10 And it wasn't me that said that. I am not giving that  
11 opinion. I am agreeing with all the evidence that we have  
12 seen.

13 Q. But that's one of the key benefits. Right?

14 A. Yes.

15 Q. And you can get that benefit from Lexion. Right?

16 A. That's not as clear to me. It's not an insufflator,  
17 let's put it that way.

18 Q. Let's go to your Slide 39, where you put up the  
19 testimony about Mr. Spearman. You indicated an assumption  
20 you made in forming your opinions about harm to SurgiQuest  
21 was that Lexion was still engaged in the conduct at issue.  
22 Right?

23 A. Actually, it was a little more subtle than that. That  
24 they would continue with the activity.

25 Q. Right. And you put up this testimony from Mr.

Ugone - cross

:55:18 1 Spearman that he mentioned something to a urologist two  
:55:22 2 weeks ago about subcutaneous emphysema. Right?

:55:25 3 A. Yes.

:55:25 4 Q. But you don't know what Mr. Spearman mentioned to the  
:55:29 5 urologist at the meeting. Right? There is no details about  
:55:34 6 the conversation, is there?

:55:39 7 A. If you were to look at all of the pages around here  
:55:42 8 and what's being discussed, I doubt if Mr. Spearman was  
:55:47 9 suddenly giving a random unrelated answer. If you want, we  
:55:53 10 can look at all the pages.

:55:54 11 Q. I have looked at the pages, sir. I don't believe  
:55:56 12 there is evidence in the record of what Mr. Spearman  
:55:58 13 discussed.

:55:59 14 THE COURT: Mr. Wille, both sides, lawyers can't  
:56:03 15 testify. Okay?

:56:04 16 Ladies and gentlemen, you will disregard that  
:56:06 17 comment.

:56:08 18 BY MR. WILLE:

:56:09 19 Q. As we sit here right now, you are not aware of what  
:56:11 20 was discussed between Mr. Spearman and the surgeon. Are  
:56:14 21 you, sir?

:56:14 22 A. No. I am just going from inference of what was being  
:56:17 23 discussed at trial.

:56:18 24 Q. And you are also making just an assumption that Mr.  
:56:21 25 Spearman said something false to the surgeon. Right?

Ugone - cross

:56:27 1 A. Actually, maybe I should clarify what my position is.  
:56:31 2 If Lexion, if the jury were to find that the information  
:56:36 3 that was being disseminated by Lexion is false in some way,  
:56:43 4 if you could monitor it and if Lexion said we will never  
:56:47 5 disseminate it again, then I would almost say you don't have  
:56:52 6 to listen to my permanent injunction opinion. It is only  
:56:55 7 under the situation where Lexion would continue to do  
:56:59 8 something the jury finds wrongful that you would need the  
:57:03 9 permanent injunction. I want to make sure that's clear.

:57:05 10 Q. Let's put up SurgiQuest 27, please.

:57:22 11 This is the exhibit that you presented on  
:57:25 12 direct. Correct?

:57:27 13 A. Yes.

:57:28 14 Q. You didn't identify any specific information in this  
:57:32 15 exhibit that was causing irreparable harm to SurgiQuest, did  
:57:36 16 you?

:57:36 17 A. Well, there was others that had done an analysis of  
:57:40 18 this. I am not the technical person. I am not the  
:57:43 19 scientist that does this. Part of my assumption is that  
:57:51 20 there will be a finding that there is, you know, wrongful  
:57:54 21 activity here. If the jury doesn't find anything wrong with  
:57:56 22 this, then it's a nonissue.

:57:58 23 Q. But this is the document that was so damaging to  
:58:02 24 SurgiQuest that Mr. Peters hadn't seen it until about a  
:58:05 25 month ago. Right?

Ugone - cross

:58:07 1 A. I believe he testified he hadn't seen it. But he had  
:58:12 2 a heavy weight on his shoulders in terms of the acquisition,  
:58:15 3 in terms of his team and everything he feels. I will not  
:58:18 4 disagree that he didn't say he hadn't seen the document  
:58:21 5 earlier.

:57:28 6 Q. Okay. And some of the information presented here is  
:57:37 7 just publicly available, peer-reviewed medical journals;  
:57:41 8 right?

:57:41 9 A. I believe to the best of my recollection, this  
:57:46 10 information was obtained from articles, yes.

:57:50 11 Q. Okay. And you're not suggesting that SurgiQuest is  
:57:54 12 irreparably harmed if Lexion provides articles from  
:57:58 13 published medical journals to customers, are you?

:58:00 14 A. No. Remember, remember what I tried to explain to the  
:58:03 15 jury, that if the jury finds that there's some wrongful  
:58:06 16 conduct here. So from a damages perspective, I always have  
:58:10 17 to assume liability. If there's no liability, then you  
:58:14 18 basically ignore what I said. It's only if you find  
:58:18 19 liability, then you consider what I'm saying.

:58:21 20 It's up to the jury to decide whether there was  
:58:24 21 misinformation provided in its articles and the use by which  
:58:29 22 Lexion was putting them.

:58:31 23 Q. Okay. Sir, are you contending or not that SurgiQuest  
:58:34 24 is irreparably harmed if Lexion provides publicly available  
:58:38 25 published medical journal articles that customers?

Ugone - cross

:58:41 1 A. If they do it in a way that's distorted.

:58:49 2 Q. Okay. So handing an article to a customer, you're  
:58:52 3 saying Lexion can't do that?

:58:55 4 A. No, that's not what I said.

:58:56 5 Q. All right. Well, isn't it possible that when  
:58:58 6 Mr. Spearman said that they wouldn't stop using the  
:59:00 7 information here, that he wanted to leave open the ability  
:59:04 8 to just hand a publicly available medical journal article to  
:59:08 9 a customer?

:59:09 10 A. Then he could have made that clearer in his testimony.

:59:12 11 Q. And you don't have any problem with that; right? You  
:59:18 12 don't think that's somehow improper for Mr. Spearman to do  
:59:22 13 that, do you?

:59:23 14 A. If there's articles that are published in  
:59:28 15 peer-reviewed journals and so they passed a test, one would  
:59:35 16 hope that the receiver of the information would take into  
:59:39 17 account the quality of the study, the ranking of the  
:59:43 18 journal, but I'm not going to say that in and of itself is  
:59:48 19 necessarily a dissemination of false information. There can  
:59:54 20 be the packaging of it. We don't know the words that are  
:59:57 21 going along with this all the time. So there's a lot of  
:00:01 22 additional issues than just, is there an article that has a  
:00:05 23 particular number in it.

:00:07 24 MR. WILLE: No further questions.

:00:08 25 THE COURT: Redirect?



Ugone - cross

:00:10 1 MS. REINCKENS: Nothing, Your Honor.

:00:10 2 THE COURT: Thank you, Doctor. Be careful  
:00:13 3 stepping down.

:00:14 4 (Witness excused.)

:00:18 5 MR. RYAN: Your Honor, that concludes  
:00:19 6 SurgiQuest's case.

:00:20 7 THE COURT: Okay.

:00:21 8 MR. WILLE: And, Your Honor, at this time we'd  
:00:23 9 like to make a motion and request to file it in writing.

:00:27 10 THE COURT: That's fine. And let me suggest to  
:00:29 11 both of you that you do that in abbreviated form.

:00:32 12 MR. WILLE: Sure.

:00:32 13 THE COURT: Bulleted, not briefed. Okay.

:00:38 14 MR. WILLE: Okay.

:00:38 15 MR. RYAN: We are already underway, so we'll do  
:00:42 16 our best to get it into bullet form, Your Honor.

:00:45 17 THE COURT: It's not going to --

:00:46 18 MR. RYAN: Understood.

:00:47 19 THE COURT: Mr. Wille, would you like us to take  
:00:49 20 our afternoon break at this time?

:00:51 21 MR. WILLE: That would be good, Your Honor.

:00:52 22 THE COURT: That would be helpful. Okay. Let's  
:00:54 23 do that.

:00:54 24 (Short recess taken.)

:21:24 25 - - -

Burban - direct

:21:24 1 (The jury entered the courtroom.)

:21:38 2 THE COURT: Ladies and gentlemen, please take  
:21:40 3 your seats.

:21:40 4 Mr. Wille?

:21:41 5 MR. WILLE: Thank you, your Honor. Lexion  
:21:44 6 recalls doctor John Burban.

:21:46 7 THE COURT: All right. Dr. Burban, consider  
:21:57 8 yourself still under oath, please. With the witness  
:21:59 9 absolutely.

:22:00 10 ... JOHN BURBAN, having been previously  
:22:03 11 duly sworn as a witness, was examined and testified  
:22:06 12 further as follows ...

:22:16 13 THE COURT: Mr. Wille?

:22:18 14 MR. WILLE: Thank you, Your Honor.

:22:18 15 DIRECT EXAMINATION

:22:19 16 BY MR. WILLE:

:22:19 17 Q. Dr. Burban, you told the jury last week about the  
:22:22 18 experiments that you did relating to air entrainment. Do  
:22:26 19 you recall that?

:22:26 20 A. Yes, I did.

:22:27 21 Q. When were those experiments done, approximately month  
:22:30 22 and year?

:22:31 23 A. I did two sets of experiments. The first one was in  
:22:33 24 December of 2015 and the second one in May 2016.

:22:37 25 Q. All right. Did you videotape those experiments?

Burban - direct

:22:41 1 A. Oh, what I did is I used my I phone to videotape the  
:22:45 2 display of the SurgiQuest unit as well as my oxygen. Then I  
:22:49 3 could use that to recreate the data that I plotted or to  
:22:52 4 recreate the data that I plotted. So, yes.

:22:54 5 Q. How far was your iPhone from the SurgiQuest unit when  
:22:57 6 you made the video?

:22:58 7 A. It was anywhere to six inches.

:23:00 8 Q. Okay. I'm going to ask Mr. Barnes to put up slide  
:23:04 9 number 2.

:23:07 10 And, Dr. Burban, what do we see here in slide  
:23:09 11 number two?

:23:10 12 A. So this is a still from the video, so it's showing --  
:23:16 13 let me get a pointer.

:23:19 14 MR. WILLE: May I approach, Your Honor?

:23:20 15 THE COURT: Yes.

:23:21 16 (Mr. Wille handed a pointer to the witness.)

:23:29 17 THE WITNESS: Thank you.

:23:33 18 So we're showing the display of the SurgiQuest,  
:23:35 19 and this is my oxygen sensor that I used, and so it's that  
:23:38 20 display as well.

:23:39 21 Q. All right. And the portion of the video that we've  
:23:43 22 chosen to play here is after you have done a leak; is that  
:23:47 23 right?

:23:47 24 A. Yes. In this particular experiment, I initiated a  
:23:51 25 16-liter, 16.3 or 16-liter minute leak.

Burban - direct

1 MR. WILLE: All right. Let me ask Mr. Barnes to  
2 play is the video, please.

3 (Videotape played.)

4 MR. WILLE: Okay. Please stop the video.

5 BY MR. WILLE:

6 Q. Did you hear three little beeps there?

7 A. Yes.

8 Q. What are those three little beeps?

9 A. That's the audible alarm that goes off when you check  
10 for excessive leakage or suction, warning shows up on a  
11 display.

12 Q. And were you here when Dr. Lee testified about a loud,  
13 obnoxious alarm?

14 A. I think he used the word horrific.

15 Q. All right. But that's the alarm that goes off; is  
16 that right?

17 A. Correct.

18 Q. Now, does that like repeat every few minutes?

19 A. No. I ran the experiment for five minutes and I only  
20 heard it once. The message stays on the display, but you  
21 don't hear any more beeps.

22 Q. Okay. And, again, is that, is the volume for that  
23 alarm adjustable?

24 A. Yes. Based on, I reviewed several manuals that had  
25 been produced during the course of this case, and in one

Burban - direct

:25:05 1 manual there were three different settings, low, medium and  
:25:08 2 high. In another manual, there were four settings.

:25:11 3 Q. Okay. Let's go to slide number 2.

:25:16 4 You had previously discussed about how the, in  
:25:20 5 your prior testimony, how the unit would shut down, and  
:25:22 6 you referred to this part of Joint Exhibit 6; is that  
:25:25 7 right?

:25:25 8 A. Yes, I did.

:25:27 9 Q. Okay. And were you asked to look at the remainder of  
:25:32 10 SurgiQuest's 510-K applications?

:25:34 11 A. Yes. As I mentioned, this is the first 510-K that was  
:25:38 12 cleared in May 2011, and this had the safety feature that  
:25:42 13 would shut down a unit following first reducing the pressure  
:25:45 14 to 12, waiting some time, noticing that the leak was  
:25:48 15 sustained, and then eventually the insufflation stops. The  
:25:52 16 unit would stop.

:25:53 17 Q. All right. And did you review engineering  
:25:55 18 documentation and deposition testimony of Mr. DeLuca to  
:26:00 19 determine when this was actually, this feature was removed  
:26:03 20 from the SurgiQuest AirSeal System?

:26:07 21 A. Yes. I reviewed the engineering change lots that were  
:26:11 22 provided as part of the overall documentation.

:26:13 23 Q. Okay. Let's go to slide number 4, please.

:26:19 24 And shown here is Lexion Exhibit 246. What is  
:26:21 25 Lexion Exhibit 246?

Burban - direct

1 A. Lexion Exhibit 246 is the summary of all the changes  
2 that were approved in April 2nd, 2012. There's signatures  
3 from World of Medicine and a signature from SurgiQuest, and  
4 this defines what happens in the presence of leaks. This  
5 says, the system should not shut down due to excessive  
6 leakage. Instead, the system should give visual and audible  
7 signals to the user to alarm them of excessive leakage while  
8 allowing the user to fix the leak.

9 I also mentioned on the first page, it  
10 talks about not reducing the pressure to 12 anymore. So  
11 this specifically addresses eliminating that safety feature.

12 Q. Okay. And let's go to the next slide, please,  
13 Mr. Barnes. Actually, I don't think -- that's the wrong  
14 slide.

15 MS. PASCAL: Objection, Your Honor.

16 MR. WILLE: That's the wrong slide, actually.

17 BY MR. WILLE:

18 Q. Okay. And SurgiQuest Exhibit 243, what's that?

19 A. SurgiQuest Exhibit 243 is the second 510-K. They  
20 mentioned they've got 4 or 510-Ks and this one was signed,  
21 dated, May 2nd, 2012, roughly a month prior to that previous  
22 document that I just described.

23 And here it says, Mr. Azarbarzin indicates  
24 that all the data and information submitted in the premarked  
25 notification are truthful and accurate and no material fact

Burban - direct

:28:03 1 has been omitted.

:28:03 2 Q. I think maybe you misspoke. What was the date of the  
:28:07 3 prior document when the software change occurred?

:28:12 4 A. It was dated 4/2/12, so January, February, March.  
:28:16 5 April 2nd.

:28:16 6 Q. And what date is this document?

:28:17 7 A. May 2nd.

:28:18 8 Q. So this is a month after?

:28:19 9 A. It's a month after.

:28:20 10 Q. Okay. I thought you said a month before, but I may  
:28:23 11 have misunderstood you.

:28:24 12 And have you reviewed the contents of  
:28:26 13 SurgiQuest's Exhibit 243?

:28:28 14 A. Yes, I have.

:28:29 15 Q. Okay. Let's go to the next slide, please.

:28:33 16 A. So in this document, SurgiQuest 243 --

:28:36 17 MS. PASCAL: I'm going to object to this  
:28:38 18 document. It's outside the scope of Dr. Burban's report  
:28:40 19 with respect to the testimony in highlighting.

:28:43 20 THE COURT: Please confer, counsel.

:28:45 21 (Pause while counsel conferred.)

:29:27 22 MR. WILLE: Your Honor, I think we have a  
:35:43 23 disagreement.

:35:43 24 THE COURT: All right. Let's see you at  
:35:43 25 sidebar.

Burban - direct

1 (Sidebar conference held out of the hearing o  
2 the jury as follows.)

3 What was the question?

4 MR. WILLE: All we're going to establish here,  
5 Your Honor, is that they are saying that the system  
6 interaction with the duo port is identical, but with the  
7 warnings and alarms. This is referring back to the  
8 predicate device, and so they are saying this works the same  
9 as the first one. That's not true.

10 THE COURT: Okay.

11 MR. WILLE: And it's covered in his report.

12 MS. PASCAL: His report did cite this section,  
13 but it made no opinion as to whether it was or was not  
14 equivalent to the duo port. In fact, he did not examine the  
15 duo port in the course of his report or any deposition  
16 testimony, and this goes on. I believe he also testified  
17 during his deposition he has no FDA experience, no  
18 experience in these type of applications.

19 We think it's highly prejudicial to put him up  
20 as an expert, have him read documents that are just, all he  
21 can do is read the words were the even on the page and give  
22 the jury the impression that he knows what should or should  
23 not come into these documents, and that applies to this and  
24 some subsequent slides I will just give Your Honor a  
25 heads-up on.



Burban - direct

:35:44 1 THE COURT: The information on this slide --  
:35:44 2 which slide is this, by the way?

:35:44 3 MR. WILLE: Slide 7.

:35:44 4 THE COURT: That's from the FDA?

:35:44 5 MS. PASCAL: Yes, Your Honor.

:35:44 6 THE COURT: Documentation?

:35:44 7 MR. WILLE: Two responses, Your Honor.

:35:44 8 Number one, he does have FDA experience. He  
:35:44 9 does deal with the FDA for his company and is involved in  
:35:44 10 creating these applications. He also interfaces with the  
:35:44 11 FDA as part of his company. We're not arguing what should  
:35:44 12 or should not be disclosed to the FDA through Dr. Burban.  
:35:44 13 That's an issue for the jury. What Dr. Burban is testifying  
:35:44 14 about is simply whether a technical feature of the product  
:35:44 15 is disclosed in the application or not and what was said  
:35:44 16 about the relationship of this device that they're  
:35:44 17 disclosing to the prior device, and that's something that a  
:35:44 18 technical expert can do.

:35:44 19 THE COURT: What does the FDA have to do with  
:35:44 20 this, Ms. Pascal?

:35:44 21 MS. PASCAL: If you would kindly show him some  
:35:44 22 of Dr. Burban's other slides, I believe you're going to  
:35:44 23 show, or we discussed at break, appears to be talking about  
:35:44 24 software changes that should or should not have been  
:35:44 25 disclosed to the FDA.

Burban - direct

:35:44 1 THE COURT: Is that what you are going to ask  
:35:44 2 him?

:35:44 3 MR. WILLE: No. No.

:35:44 4 THE COURT: It's perhaps anticipating --

:35:44 5 MS. PASCAL: I'm going on the titles. They all  
:35:45 6 say software change, the ones with you gave us.

:35:45 7 MR. WILLE: He's simply going to explain that as  
:35:45 8 a factual matter, they had a software change log that they  
:35:45 9 provided to the FDA. The software change log will miss the  
:35:45 10 fact that the shutdown feature was removed. He does not  
:35:45 11 have to be a software expert to know that. That's something  
:35:45 12 fully within his capability as an engineer. He reviews  
:35:45 13 engineering change logs all the time.

:35:45 14 MS. PASCAL: Let me be heard briefly.

:35:45 15 So the FDA has specific requirements. There are  
:35:45 16 many software changes that do not need to be disclosed,  
:35:45 17 don't belong in these applications. And he testified at  
:35:45 18 deposition, have you ever been involved in 510-K  
:35:45 19 applications that involve devices using software? No. None  
:35:45 20 of our device use software.

:35:45 21 Have you ever been involved in 510-K changes  
:35:45 22 that involve control methods? No. As I mentioned, none of  
:35:45 23 the device I have direct involvement with have software, so  
:35:45 24 there really isn't a control mechanism present.

:35:45 25 The only FDA experience he did testify to is he

Burban - direct

1 only had on-the-job training. He had never taken a formal  
2 course, nor had he been a consultant. So if his on-the-job  
3 training was related to his devices, he cannot opine and  
4 give the jury the impression that this software log is what  
5 is or isn't there has any bearing on this case, because that  
6 would imply by pointing out that it's not there, that there  
7 was a requirement.

8 And --

9 THE COURT: Is that what you are trying to have  
10 the jury inferred?

11 MR. WILLE: Absolutely not, your Honor. He is  
12 not going to talk about what the FDA requires or not. The  
13 evidence here will show that the FDA specifically asks.

14 THE COURT: Let me interrupt for a second.  
15 Well, finish that thought.

16 MR. WILLE: The FDA specifically asked for a  
17 list of the software changes. That list was provided, and  
18 missing from the list of software changes was the fact that  
19 the shutdown feature was removed. That's something he's  
20 capable of testifying to.

21 THE COURT: Why can't he talk about the  
22 technical information that was or was not provided?

23 MR. WILLE: Because by doing that, he implies to  
24 the jury that he has expertise that it should have been  
25 provided to him.

Burban - direct

1           What I'm trying to express to Your Honor is  
2           there's actually a deliberate process that FDA has that you  
3           have to go through, and it actually is a flowchart and a  
4           regulatory consultant who knows the law and makes a choice,  
5           and one of the choices is, do not report. Please document  
6           internally.

7           And so if we had a regulatory, or one of us  
8           did have here, they could say it was missing and that is  
9           material to this case somehow. I'm not sure how. But by  
10          implying whether it's there or not, it implies to the  
11          jury it should have been there, and neither of us have  
12          regulatory --

13          THE COURT: It sounds like Ms. Pascal complains  
14          about the relevance of his testimony.

15          MR. WILLE: The relevance of the testimony, Your  
16          Honor, is that they've created the impression with the jury  
17          that the FDA has blessed what they are doing in terms of the  
18          removal of the shutdown feature. Mr. Azarbarzin on the  
19          redirect talked about how there had been FDA audits and the  
20          FDA had come in and audited their business. We are not  
21          arguing about this flow chart that Ms. Pascal refers to.  
22          This is a case where the FDA made a specific request.  
23          There's a question. It's in writing. They made a specific  
24          request for information and SurgiQuest gave them the wrong  
25          information.

Burban - direct

:35:47 1 MS. PASCAL: I think it's in that judgment, your  
:35:47 2 Honor. I realize --

:35:47 3 THE COURT: I think the jury can filter this and  
:35:47 4 you're going to cross-examine him about this. Right?

:35:47 5 MS. PASCAL: I understand that, but in my point  
:35:47 6 of view, and I will just conclude --

:35:47 7 THE COURT: They can handle this. Overruled.

:35:47 8 (End of sidebar conference.)

:36:17 9 Q. Can we have that slide back up, please, Mr. Barnes.

:36:26 10 Dr. Burban, what is the page you are showing  
:36:29 11 here from Exhibit 243?

:36:31 12 A. Exhibit 243 is the Section 8 in the document called  
:36:35 13 Rationale For Substantial Equivalence. And what it does is,  
:36:40 14 it's saying that the device in question, which is the second  
:36:44 15 510(k), it's indicating that the substantially equivalent  
:36:50 16 device is this 510(k), which is the very first 510(k).

:36:54 17 It further states that the subject SurgiQuest  
:36:57 18 device and the predicate device are equivalent in all major  
:37:01 19 regards.

:37:02 20 On the bottom it indicates the capital system  
:37:05 21 interaction with the Duoport -- the Duoport, that was the  
:37:08 22 name for this. It was two ports associated with the iFS.  
:37:10 23 It was called their Duoport, the identical -- the warnings  
:37:14 24 and alarms were deadline.

:37:15 25 Q. Dr. Burban, based upon your review of Exhibit 243,

Burban - direct

:37:18 1 what is the Capital System?

:37:20 2 A. The Capital System is the box that contains all the  
:37:25 3 components in a box that sends the box and interacts with  
:37:28 4 the trocar.

:37:28 5 Q. Based upon your review of Exhibit 243, is there any  
:37:32 6 disclosure of the removal of the shutdown feature?

:37:35 7 A. Absolutely not.

:37:35 8 Q. Was there any disclosure of Mr. Stearns's test data or  
:37:40 9 was there any disclosure of Mr. Stearns test data regarding  
:37:44 10 the percentage of air that can be in the abdomen?

:37:46 11 A. No.

:37:46 12 Q. Was there any disclosure of SurgiQuest's patent that  
:37:50 13 the jury has seen during this case?

:37:53 14 A. No.

:37:53 15 Q. Okay. Let's go to the next slide, please.

:38:01 16 Did the FDA come back and ask questions to  
:38:03 17 SurgiQuest about the second 510(k)?

:38:06 18 A. Yes. So on May 23rd, this indicates that the FDA sent  
:38:12 19 in a response for additional information, and then on June  
:38:15 20 18th, 2012, Mr. Daniel Donovan, the signature here,  
:38:22 21 submitted the response to the FDA, indicating, here is the  
:38:25 22 sentence, "We are confident that we have accurately and  
:38:28 23 comprehensively answered the questions ahead of us and  
:38:32 24 eagerly anticipate FDA approval our submission."

:38:36 25 Q. Let's go to the next slide. Could you just please

Burban - direct

:38:41 1 explain, how does the FDA ask these questions?

:38:44 2 A. The FDA will send you an e-mail, with those types of  
:38:50 3 questions, or work through your regulatory consultant. It  
:38:56 4 depends on those situations. They review the information  
:38:58 5 that has been submitted and then they look at what's been  
:39:01 6 provided, and determine whether or not they need additional  
:39:05 7 information to really evaluate if the information provided  
:39:09 8 can be used.

:39:12 9 Q. Question No. 5, what was the FDA inquiring about?

:39:16 10 A. The FDA in Question 5 inquired about the device  
:39:20 11 description. In reviewing the second 510(k), this language  
:39:24 12 in the device description did not exist. This language came  
:39:28 13 from the first 510(k).

:39:30 14 So the FDA was told that it's the same, so  
:39:33 15 they -- I found that language in the first 510(k). So they  
:39:38 16 are asking about the safety feature, including the CO2  
:39:42 17 sensor, and wanting to know if the change to using the  
:39:47 18 Duoport affected the performance of the system as relates to  
:39:51 19 shutting down that safety feature.

:39:53 20 Q. What did SurgiQuest respond?

:39:55 21 A. They responded that the new system using the same  
:39:59 22 software in response and accuracy to the CO2 levels does not  
:40:04 23 change.

:40:04 24 Q. Based upon your testing, is that true?

:40:09 25 A. That is not true.

Burban - direct

:40:09 1 Q. Let's go to the next slide, Joint Exhibit 34, what is  
:40:16 2 Joint Exhibit 34?  
:40:17 3 A. Joint Exhibit 34 is the fourth 510(k) application for  
:40:22 4 an iFS system. This one had a new indication for additional  
:40:26 5 surgical procedures called TIMS (phonetic).  
:40:28 6 Q. And what did SurgiQuest tell the FDA with respect to  
:40:33 7 changes to the control mechanism?  
:40:35 8 A. They said there is no change to the control mechanism.  
:40:39 9 I might add, this was filed in 2014.  
:40:43 10 Q. Let's go to the next slide, please. Who is Mr.  
:40:49 11 DeLuca?  
:40:49 12 A. Mr. DeLuca was a quality manager at SurgiQuest.  
:40:51 13 Q. What did Mr. DeLuca testify to regarding the control  
:40:56 14 mechanism change?  
:40:57 15 A. In his deposition, he did indicate that there was a  
:41:00 16 change in a control mechanism, so that the unit would not  
:41:04 17 shut down after multiple minutes of detecting air  
:41:07 18 entrainment. So that safety feature was eliminated and it  
:41:11 19 was the change in control mechanism.  
:41:13 20 Q. Let's go to the next slide, please. Did SurgiQuest  
:41:17 21 get questions from the FDA on this application as well?  
:41:21 22 A. Yes, they did. The FDA examiner sent questions, and  
:41:26 23 then Mr. Donovan again replied, saying we are confident that  
:41:30 24 we have accurately and comprehensively answered the  
:41:32 25 questions.



Burban - direct

:41:32 1 Q. Is this Joint Exhibit 70?

:41:35 2 A. This is Joint Exhibit 70?

:41:40 3 Q. Let's go to the next slide. What was Question No. 4,  
:41:43 4 what was the FDA asking for?

:41:44 5 A. Specifically in Question No. 4 of Joint Exhibit 70,  
:41:48 6 the FDA examiners requested a detail summary of the changes  
:41:53 7 made in each revision and release of each revision in a  
:41:56 8 section entitled Software.

:41:57 9 Q. Let's go to the next slide, please. Is this  
:42:04 10 SurgiQuest's response shown here?

:42:06 11 A. This is SurgiQuest's response for a change dated back  
:42:10 12 in 2012, which is consistent with the date of the  
:42:13 13 engineering change to eliminate the safety feature that  
:42:16 14 reduced both the pressure and shut off -- did not shut off  
:42:20 15 the unit. This is the summary of the changes that were made  
:42:24 16 to that device. And they do indicate no pressure drop  
:42:29 17 during an excessive leak in AirSeal method.

:42:33 18 What I found what was missing is they don't say  
:42:35 19 they don't shut the unit off anymore.

:42:37 20 Q. Was there any disclosure in this 510(k) application of  
:42:40 21 Mr. Stearns's test data?

:42:43 22 A. No.

:42:43 23 Q. Was there any disclosure of the results of that test,  
:42:46 24 that over 70 percent air could be in the abdomen?

:42:49 25 A. No.

Burban - cross

:42:49 1 Q. Was there any disclosure of SurgiQuest's patent?

:42:52 2 A. No.

:42:53 3 MR. WILLE: No further questions.

:42:56 4 THE COURT: Your witness.

:42:57 5 CROSS-EXAMINATION

:42:57 6 BY MS. PASCAL:

:42:58 7 Q. Good afternoon, Dr. Burban.

:43:03 8 A. Good afternoon.

:43:04 9 Q. Now, I understand, you are being compensated for your  
:43:07 10 time here. Is that right?

:43:08 11 A. I am.

:43:08 12 Q. That has been true throughout this whole case.

:43:11 13 Correct?

:43:11 14 A. Yes.

:43:11 15 Q. You have never worked for the FDA. Is that right?

:43:15 16 A. That is correct.

:43:15 17 Q. You have no formal training in FDA regulation. Is  
:43:19 18 that correct?

:43:19 19 A. I just have on-the-job training in my every-day work.

:43:22 20 Q. In your on-the-job training you have never filed an  
:43:25 21 application for a 510(k) for an insufflator. Is that right?

:43:28 22 A. That is correct.

:43:29 23 Q. And you have never filed a 510(k) application like the  
:43:32 24 ones we have been looking at for trocar. Correct?

:43:35 25 A. For trocar, that is correct.

Burban - cross

:43:37 1 Q. And you have also never been involved in devices that  
:43:40 2 involve, medical devices that involve software. Correct?  
:43:45 3 A. Let me think back through my experience.  
:43:48 4 At Hemostasis, no.  
:43:52 5 Q. So you have never filed a 510(k) application that  
:43:55 6 involved a medical device with a change to software.  
:43:58 7 Correct?  
:43:59 8 A. Correct.  
:43:59 9 Q. Now, the FDA documents you have shown us, you have not  
:44:06 10 seen any evidence in the case of the FDA itself having any  
:44:10 11 complaints with regard to what was disclosed to it.  
:44:13 12 Correct?  
:44:13 13 A. No, the FDA only knows what is provided to them.  
:44:16 14 Q. You know Mr. Azarbarzin is going to testify -- I  
:44:19 15 believe it might have been also Mr. Peters, that the FDA  
:44:22 16 does regular audits of and comments at SurgiQuest. Correct?  
:44:28 17 A. I have been participating in audits and I work at  
:44:32 18 Hemostasis. So, yes, they did indicate that. So I have  
:44:34 19 some familiarity with audits.  
:44:36 20 Q. You talked about control mechanisms. Are you aware  
:44:39 21 that is actually a particularized term with regard to how  
:44:42 22 the FDA reviews software?  
:44:46 23 A. I saw it in the FDA document, and the response from  
:44:50 24 Mr. DeLuca.  
:44:51 25 Q. So you would understand that you would have to have

Burban - cross

:44:54 1 experience in these type of regulations to make judgment as  
:44:57 2 to whether your software change was a control mechanism  
:45:01 3 change or a change that fell under another FDA category.  
:45:05 4 Correct?

:45:05 5 A. A control mechanism change that eliminates a safety  
:45:08 6 feature seems to be a significant control mechanism change.  
:45:11 7 It changes the unit that is controlled, based on the  
:45:14 8 feedback from its sensors.

:45:15 9 Q. That is based on your reading off the FDA's website.  
:45:20 10 Is that right?

:45:20 11 A. That is based on reading the testimony in this case  
:45:22 12 and certainly I do go on the FDA website to learn.

:45:28 13 Q. You have never seen the FDA identify any particular  
:45:31 14 aspects of the AirSeal software as a control mechanism.  
:45:34 15 Isn't that correct?

:45:36 16 A. Again, I say the FDA only responds to information  
:45:39 17 provided to the them.

:45:40 18 Q. You realize that the FDA has a flowchart process where  
:45:45 19 if you had FDA regulation experience you would understand  
:45:48 20 that some software changes don't have to be reported to the  
:45:52 21 FDA? Do you understand that?

:45:54 22 A. That is correct. The changes that don't result in  
:45:56 23 changes of safety and effectiveness do not need to be  
:46:00 24 reported to the FDA. The company is responsible for  
:46:04 25 documenting those changes, that are then reviewed or may be

Burban - cross

:46:07 1 reviewed when an auditor comes to visit to verify that all  
:46:12 2 the documentation within the company complies with ISO  
:46:14 3 standards and so forth for medical device manufacturers.

:46:16 4 Q. Mr. Splansky, if you could pull up JTX-34, I believe  
:46:20 5 this is one of the FDA documents you reviewed as part of  
:46:24 6 this case. Mr. Splansky, if you could go to Bates No.  
:46:39 7 SQ-0080699.

:46:51 8 Dr. Burban, in this application that you  
:46:53 9 reviewed, if we could highlight the second paragraph that  
:46:56 10 begins A gas sensor, you see there that SurgiQuest told the  
:47:04 11 FDA, if the carbon dioxide level drops, the flow of carbon  
:47:08 12 dioxide delivered to the abdomen through the insufflation  
:47:12 13 lumen is increased. If the carbon dioxide level remains low  
:47:15 14 for more than two minutes then a visual and acoustic warning  
:47:18 15 is activated.

:47:19 16 Do you see that?

:47:20 17 A. Yes.

:47:20 18 Q. If we zoom out, and we zoom to the next paragraph, you  
:47:24 19 will see, it does not go on to say that the unit is going to  
:47:28 20 shut down. Correct?

:47:29 21 A. Yes. This document is from 2014. The change was made  
:47:36 22 in 2012. I didn't see the description in the 2014 510(k).  
:47:41 23 This is two years after they made the change. If you look  
:47:44 24 at what the examiner asks, he specifically asks for a  
:47:48 25 summary of the changes, and it is not in there?

Burban - cross

:47:50 1 Q. You made a judgment it should have been there in 2012  
:47:54 2 without having FDA experience. Can we establish that?

:47:58 3 A. The FDA was told that the software is the same. Why  
:48:03 4 would they expect there to be a change?

:48:04 5 Q. You didn't make an examination of the software in this  
:48:07 6 case, did you?

:48:09 7 A. I noted the software that I was using during my test  
:48:13 8 to be careful in documenting in everything, and I reviewed  
:48:16 9 the change logs for the different functions of the software.

:48:19 10 Q. But you didn't do any comparison of software code in  
:48:22 11 this case. Is that right?

:48:24 12 A. No. The description of the software changes indicated  
:48:28 13 what changed with the software.

:48:29 14 Q. And you understand that the period of time we are  
:48:31 15 dealing with in this case, the damages period, is 2013 to  
:48:35 16 2015. Right?

:48:37 17 A. Yes.

:48:37 18 Q. Let's go back to what you identified as the '14  
:48:46 19 application. If we can turn to Page 80701. If we could  
:48:53 20 focus on the second paragraph under Software. Do you see  
:49:01 21 there that it tells the FDA that the company has a mechanism  
:49:04 22 in place with their quality management system for evaluating  
:49:10 23 whether or not a proposed change to a device meets the  
:49:12 24 regulatory threshold for the 510(k). Do you see that?

:49:16 25 A. I see that. Every company that produces medical

Burban - cross

1 devices has to have a quality management system in place to  
2 evaluate any changes to the device that they put on the  
3 market to make sure it's safe for use.

4 Q. If we could go to the next page, Mr. Splansky. And  
5 just focus in on the top paragraph when you get there. You  
6 see, if we start at The changes are documented, like you  
7 testified that companies document, the changes are  
8 documented in the SurgiQuest AirSeal iFS DeviceMaster record  
9 in accordance with the FDA good manufacturing practices  
10 regulations and applicable standards.

11 Do you see that?

12 A. Yes, I see that.

13 Q. To your knowledge, the FDA has not taken that  
14 statement and provided any evidence that they have a problem  
15 with the documentation that remains at SurgiQuest?

16 A. They only know it was provided to them. They do not,  
17 in my experience, the FDA does not evaluate the actual  
18 physical device for these types of devices. I have  
19 participated in classes for Class 2 devices. They don't  
20 actually operate the device to see how it works. They take  
21 your word for it that you are doing the right thing and you  
22 supplied them all the information, because there is  
23 consequences if you don't. And companies shouldn't take  
24 those risks.

25 MS. PASCAL: Thank you. No further questions,

1 Your Honor.

2 MR. WILLE: No redirect, Your Honor.

3 THE COURT: Thank you, Doctor.

4 (Witness excused.)

5 MR. WILLE: Your Honor, Lexion calls Dr. Jay --  
6 recalls Dr. Jay Redan.

7 ... JAY A. REDAN, having been previously sworn  
8 as a witness, was examined and testified further as  
9 follows ...

10 THE COURT: Doctor, you are still under oath.

11 DIRECT EXAMINATION

12 BY MR. WILLE:

13 Q. Good afternoon, Doctor.

14 I am going to ask Mr. Barnes to put up a slide  
15 that was used with Dr. Ramirez, Slide 10 from Dr. Ramirez's  
16 presentation. There is a couple of arrows on your screen.  
17 If you click in the corner of the screen, it might take them  
18 away. So Dr. Ramirez presented a series of articles to the  
19 jury dealing with heating and human differentiation. What  
20 do you understand the pink ones to represent?

21 A. Those are articles that used Insuflow or part of the  
22 article used Insuflow in its article summary.

23 Q. Okay. Please identify the author of each of those  
24 articles simply so we have a written record of the authors  
25 of the Insuflow article?



:51:29 1 A. The heat and humidifying beneficial column, Dr. Ott,  
:51:33 2 Dr. Benzo, Dr. Benevides, Dr. Almeda, Dr. Johnson, Dr.  
:51:37 3 Weizman. Dr. Balasek, Dr. Sagee, Dr. Humsa. Heat and  
:51:43 4 humidity, not beneficial column, Dr. Birch, Dr. Champion,  
:51:47 5 Dr. Yeh, Dr. Savel, Dr. Farley.

:51:51 6 Q. With respect to the articles you just identified, how  
:51:53 7 many of those are published in peer-reviewed medical  
:51:56 8 journals?

:51:56 9 A. 100 percent.

:51:58 10 Q. Okay. And are you a peer reviewer on any of those  
:52:01 11 journals?

:52:01 12 A. Yes. In my testimony, I'm on the editorial board of  
:52:07 13 Surgical Endoscopy. I'm also a peer reviewer on that board  
:52:11 14 as well.

:52:11 15 Q. All right. I want to show you something Dr. Ramirez  
:52:13 16 said during his testimony. Could we put up slide 20,  
:52:16 17 please, Mr. Barnes.

:52:19 18 Do you see the last sentence of Dr. Ramirez's  
:52:33 19 testimony where he referred to these journals as throw-away  
:52:36 20 journals?

:52:37 21 Do you see that?

:52:37 22 A. Yes, I do.

:52:38 23 Q. And do you agree these are throw-away journals?

:52:41 24 A. No. These are, as you mentioned, peer-reviewed  
:52:44 25 journals. Specifically, I know JSLS is downloaded over a

:52:48 1 100,000 times per month. People actually have to physically  
:52:51 2 go to that website, have to download those journals.  
:52:55 3 Someone downloading something 100,000 times a month, I doubt  
:52:58 4 it's a throw-away journal.

:52:59 5 Q. Okay. You indicated you're a peer reviewer. Which of  
:53:02 6 those journals are you a peer reviewer for?

:53:05 7 A. JSLS. Surgical Endoscopy as well.

:53:09 8 Q. Is Dr. Ramirez a member of any of the organizations  
:53:13 9 that published the journals that are shown here?

:53:16 10 A. He was a member of JSLS as well, and I know he's a  
:53:21 11 current member of AAGL.

:53:24 12 Q. Okay.

:53:25 13 A. The first column.

:53:25 14 MR. WILLE: Can I have slide number 2,  
:53:27 15 Mr. Barnes, from our presentation?

:53:28 16 BY MR. WILLE:

:53:40 17 Q. Dr. Redan, we have SurgiQuest Exhibit 28 here shown on  
:53:45 18 slide number 2. Did you receive this from Dr. Ott?

:53:50 19 A. Yes, I did.

:53:51 20 Q. So you didn't just receive it in this case. He  
:53:53 21 actually sent you a copy at the time that he sent it out; is  
:53:56 22 that correct?

:53:56 23 A. Yes. Several years ago.

:53:58 24 Q. What did you understand it to convey?

:54:03 25 A. That the -- comparing the AirSeal valveless system to

1 conventional trocars, there's a much higher instance of  
2 subcutaneous emphysema, twice the instance of  
3 pneumomediastinum, three times the instance of pneumothorax  
4 as noted in those five peer-reviewed journal articles.

5 Q. All right. And what was your reaction when you got  
6 this?

7 A. That obviously the AirSeal System has the higher  
8 incidence of complications compared to conventional  
9 trocars.

10 Q. And what medical journal articles did Dr. Ott use to  
11 create his graft?

12 A. So he used one by Dr. Selik in JSLS. Two by doctor  
13 Herati, one in the journal Endourology, 2009. One by Dr.  
14 Herati, Urology, 2011. Dr. Hillisohn, the Journal of  
15 Urology, 2013, and also Dr. Horstmann, Journal of Urology,  
16 2013.

17 Q. What are the exhibit numbers of those articles?

18 A. I'm sorry. The first, Selik, Exhibit 21. Herati,  
19 2009, Exhibit 193. Herati 2011, Exhibit 185. Hillisohn,  
20 Exhibit 22, and Horstmann, Exhibit 19.

21 Q. Okay. To your knowledge, at the time Dr. Ott prepared  
22 this chart, what other medical journal articles reporting  
23 complication rates were available for Dr. Ott to use?

24 A. Zero. None others.

25 Q. Okay. And what medical journals are you aware of that

1 report lower rates of complications with AirSeal?

2 A. None.

3 Q. Okay. Let's go to the next -- let's go to slide  
4 number 4, please, Mr. Barnes.

5 So what, actually -- let's step back for a  
6 moment. Dr. Ott reports standard rates in his graph for  
7 subcutaneous emphysema, pneumothorax and pneumomediastinum  
8 number; is that correct?

9 A. Yes.

10 Q. Is there some sort of agreed-upon rate, standard rate  
11 for all of those in the medical community?

12 A. No, there's not. I think there's -- any reasonable  
13 surgeon has to use their judgment as to what they think is  
14 expected, and Dr. Ott used judgment in what he thought was  
15 appropriate to present in this letter.

16 Q. Okay. So do you recall that Dr. Ott used 1.9 percent  
17 for his number for pneumomediastinum number?

18 A. Yes. As a matter of fact, in the article listed here,  
19 Dr. Murdock, she actually combined the pneumomediastinum  
20 number and pneumothorax to come up with about 1.9 percent.  
21 It's in agreement with what Dr. Ott stated in the letter.

22 Q. All right. So what is your opinion as to whether Dr.  
23 Ott had adequate support for the 1.9 percent number he  
24 chose?

25 A. Dr. Ott's conclusion is peer-reviewed evidence based

:56:40 1 on this medicine.

:56:41 2 Q. And you refer to the Murdock article. Is that Lexion  
:56:44 3 Exhibit 445?

:56:45 4 A. Yes. Lexion Exhibit 445.

:56:47 5 Q. And how many different surgeries did Dr. Murdock look  
:56:50 6 at to arrive at that rate?

:56:51 7 A. 968. Large number.

:56:54 8 Q. All right. Let's go to the next slide, please. What  
:56:57 9 is Lexion Exhibit 171?

:57:00 10 A. Lexion Exhibit 171 is the letter from, SurgiQuest  
:57:04 11 letter to Dr. Miller, one of their customers, showing the  
:57:07 12 1.9 percent pneumothorax rate and 1.9 percent  
:57:10 13 pneumomediastinum rate, which is the same number that Dr.  
:57:15 14 Ott came up with in his e-mails.

:57:18 15 Q. And the article cited in Footnote 1, what article is  
:57:22 16 that?

:57:22 17 A. That is the hyper --

:57:27 18 Q. Okay. Can we go to the next slide, please. Dr.  
:57:31 19 Ott -- sorry.

:57:33 20 Dr. Redan, is there a further support in the  
:57:35 21 literature for even lower rates of pneumomediastinum number  
:57:39 22 than what Dr. Ott shows?

:57:40 23 A. Yes. Lexion Exhibit 367 by Dr. Sharma. 0.08 percent  
:57:46 24 risk of pneumomediastinum, which actually is favorable to  
:57:50 25 SurgiQuest by a factor of 20, showing -- 20 times less than

1 the 1.9 percent.

2 Q. And how many publications does Dr. Sharma review to  
3 publish his article?

4 A. This is, again, meta-analysis, this grouping of  
5 publications is 152 articles.

6 Q. Let's go to the next slide, please. What is your  
7 opinion as to whether Dr. Ott's use of 0.4 percent for  
8 subcutaneous emphysema is supported by the literature?

9 A. Again, Dr. Murdock's article is supported, .43 to  
10 2.34. Dr. Ott chose a conservative number, 2.3 percent,  
11 2.4. There is a variation. Again, it's judgment, however,  
12 the numbers are peer-reviewed and supported in this letter.

13 Q. And SurgiQuest's letter shown here, Lexion Exhibit  
14 171. Is that right?

15 A. Yes.

16 Q. What rate did SurgiQuest choose for its graph?

17 A. So SurgiQuest chose 2.3 percent.

18 Q. So did SurgiQuest choose the upper end of the range  
19 and Dr. Ott choose the lower end of the range?

20 A. Yes, it's all within that range. Again, it's all due  
21 to judgment of the author.

22 Q. Next slide, please.

23 What is Lexion Exhibit 744?

24 A. Lexion Exhibit 744 is the study cited by Dr. Lee, a  
25 separate Dr. Lee. There is a lot of Dr. Lee's here. Dr.

1 Lee, the urologist, cited Dr. Lee, the gynecologist, in this  
2 article, suggesting subcutaneous emphysema being between .3  
3 to 3.9 percent. Dr. Lee's study of Dr. Lee cites similar  
4 statistics.

5 Q. Let's go to the next slide, please. What is your  
6 opinion as to whether Dr. Ott had support in the literature  
7 for his choice of 0.4 percent for the rate of pneumothorax?

8 A. Lexion Exhibit 22 shows very clearly the risk of a  
9 valveless trocar system, the AirSeal system, that the  
10 pneumothorax incidence is between .4 and .7 percent. Again,  
11 his numbers are well supported in the peer-reviewed medical  
12 literature.

13 Q. Let's go to the next slide, please. What is your  
14 belief as to whether the -- what is your belief as to  
15 whether the rate chosen by Dr. Ott is favorable to  
16 SurgiQuest?

17 A. In Lexion Exhibit 367, also part of Dr. Sharma's  
18 journal article, pneumothorax develops in 0.03 percent of  
19 cases, so Dr. Ott is favorable to SurgiQuest by a factor of  
20 13.

21 Q. Now, Dr. Lee reported a range of rates, and he didn't  
22 really go into the articles where he got those, but he  
23 reported a range of rates for each of these complications.  
24 Have you reviewed the literature from Dr. Lee's expert  
25 report regarding the range that Dr. Lee produced?

1 A. Yes. He reviewed five articles to develop a range of  
2 subcutaneous emphysema. As testified to earlier by Mr.  
3 Tegan, Dr. Lee's articles all are about retroperitoneal  
4 surgery. These are specific type of surgeries, type of  
5 cardio surgeries, neurology procedures, where he  
6 deliberately as part of the surgical procedure created  
7 subcutaneous emphysema by going outside that layer that  
8 keeps the gas in the belly.

9 All Dr. Ott's articles refer to intraperitoneal,  
10 or gas inside the abdomen.

11 So this is apples and oranges. Dr. Lee's  
12 references have absolutely no correlation to Dr. Ott's  
13 conclusion. Totally separate.

14 Q. Please explain to the jury why a doctor would want to  
15 deliberately create a subcutaneous embolism?

16 A. So when you are approaching a kidney, sometimes  
17 approaching a hernia, the best access to get to these  
18 organs, your kidney is in your back, so you may want to go  
19 behind the belly, behind your abdomen to get to that organ  
20 or an adrenal gland.

21 There are some organs back there. The hernia is  
22 either in your groin, sometimes they are outside of the  
23 abdomen. So you want to stay in a separate tissue plane to  
24 get to your target organ.

25 Actually a very good way to do that is to



1 deliberately create a subcutaneous emphysema or what's  
2 called extraperitoneal surgery. But -- it's a technical  
3 thing. But it does create a sub-embolism. I think this was  
4 a little confusing, the articles Dr. Lee showed you, to make  
5 you think there was a problem. There is not.

6 Q. And let's have the next slide, please, Mr. Barnes. Do  
7 you have other criticisms of the studies that Dr. Lee used  
8 with respect to whether the findings were clinical or  
9 subclinical?

10 A. Yes. Lexion Exhibit 742, Dr. Abreu, what they did was  
11 a retrospective analysis. They took 1,129 patients. Their  
12 surgery was completed. They went back and looked at the  
13 x-rays, and they saw that of those people, that only 45  
14 percent -- 45 percent didn't even need an x-ray but 71  
15 percent were completely normal. So 29 percent of those were  
16 read by the radiologist were not normal, so they may have  
17 seen some air bubbles in an x-ray and called it abnormal for  
18 academic purposes. But those patients had no reason  
19 otherwise to have an x-ray. It's just an academic exercise.  
20 Nothing that we would call clinically significant.

21 Q. Okay. And what is a subclinical complication?

22 A. They may have had a finding on an x-ray but didn't  
23 have any symptoms, like a little air bubble under their  
24 skin. It didn't bother them, didn't cause any shortness of  
25 breath or trouble breathing.

Redan - cross

:04:38 1 Q. Did the term have any meaning as to whether the doctor  
:04:42 2 detected the subcutaneous emphysema during the procedure or  
:04:44 3 after that?

:04:45 4 A. That's correct. They probably didn't have suspicion  
:04:47 5 that they had anything. They looked fine, fine, see, you  
:04:52 6 look fine, there would be no reason for me to do an x-ray on  
:04:55 7 you because you wouldn't have any physical findings.

:04:58 8 MR. WILLE: No further questions.

:05:00 9 THE COURT: Ms. Pascal.

:05:02 10 MS. PASCAL: Thank you, Your Honor.

:05:06 11 CROSS-EXAMINATION

:05:07 12 BY MS. PASCAL:

:05:07 13 Q. Dr. Redan, you are a paid expert in this case. Is  
:05:14 14 that right?

:05:14 15 A. Yes.

:05:14 16 Q. As of your deposition, in October 2016, you had  
:05:19 17 already been compensated for about 150 to 200 hours in this  
:05:22 18 case. Is that right?

:05:22 19 A. I haven't been paid yet.

:05:24 20 Q. But you are charging Lexion for your time. Correct?

:05:28 21 A. Yes.

:05:28 22 Q. That is at \$500 an hour?

:05:30 23 A. Yes.

:05:30 24 Q. Mr. Splansky, if you could up put up Trial Exhibit  
:05:37 25 SQ-26, I believe you just testified that you received a

Redan - cross

:05:42 1 chart from Dr. Ott prior to your engagement in this  
:05:45 2 litigation. Correct?

:05:46 3 A. Yes.

:05:47 4 Q. And in this e-mail here, February 7, 2014, that  
:05:54 5 last -- I am just going to borrow the pointer from Mr.  
:06:00 6 Splansky if it is available. This last name here, that's  
:06:04 7 you?

:06:05 8 A. That's me, yes.

:06:06 9 Q. And Dr. Ott, his e-mail, that is actually his personal  
:06:13 10 e-mail address, isn't it?

:06:15 11 A. Yes.

:06:15 12 Q. And he did not use his Lexion e-mail address on this  
:06:20 13 e-mail, did he?

:06:21 14 A. It does not say that, that's correct.

:06:23 15 Q. And as of this time, I believe you weren't yet engaged  
:06:26 16 as an expert in this case. Right?

:06:28 17 A. No.

:06:29 18 Q. If we pull out, take the callout down, the e-mail you  
:06:33 19 received from Dr. Ott didn't identify along with the chart  
:06:38 20 that Lexion was actually in litigation with SurgiQuest, does  
:06:42 21 it?

:06:43 22 A. No.

:06:43 23 Q. He didn't include that information in his e-mail to  
:06:47 24 you and your colleague?

:06:48 25 A. He did not, no.

Redan - cross

:06:49 1 Q. And if we again take down the callout and look at  
:06:56 2 this, there are a number of journal articles listed at the  
:06:59 3 bottom of the chart. Correct?

:07:01 4 A. Yes.

:07:01 5 Q. And those articles relate to the AirSeal system, don't  
:07:06 6 they?

:07:06 7 A. Yes.

:07:06 8 Q. And, again, if you could take that down again, Mr.  
:07:11 9 Splansky.

:07:11 10 Your e-mail that you received from Dr. Ott  
:07:14 11 didn't cite any articles where Dr. Ott had calculated these  
:07:19 12 green bars for the conventional insufflation. Correct?

:07:23 13 A. Not in this e-mail, no.

:07:25 14 Q. And from your review of this case, this e-mail with  
:07:30 15 the chart, this was pretty much what many surgeons received  
:07:34 16 from Dr. Ott when he set sent out this information.  
:07:38 17 Correct?

:07:39 18 A. You would have to ask Dr. Ott who he sent it to. I  
:07:43 19 can only testify as to what I received.

:07:44 20 Q. Did you not review in the course of this case the  
:07:46 21 other e-mails, that are about a hundred e-mails, we heard  
:07:51 22 Dr. Ott sent out on that video?

:07:54 23 A. I know obviously of at least two others and I know he  
:07:58 24 sent out a lot to other people.

:08:00 25 Q. If we take out the callout, the e-mail that he sent

Redan - cross

:08:03 1 out to others was similar to yours, it didn't include any  
:08:06 2 information where one could figure out just from the e-mail  
:08:09 3 where these green bars came from. Correct?  
:08:11 4 A. Not that I recall.  
:08:11 5 Q. In fact, you, yourself, up until you got engaged in  
:08:16 6 this case didn't do any research to find out how those green  
:08:20 7 bars were calculated. Correct?  
:08:23 8 A. I did now and I found them to be accurate.  
:08:25 9 Q. I am asking you, prior to this case when you received  
:08:27 10 this as a normal practicing surgeon, not an expert, you  
:08:31 11 didn't do anything to figure out where those green bars came  
:08:34 12 from?  
:08:34 13 A. Correct. No, I trust Dr. Ott, because he is an expert  
:08:37 14 in this area.  
:08:37 15 Q. You just took them at face value. Correct?  
:08:42 16 A. Yes.  
:08:42 17 MS. PASCAL: No more questions.  
:08:46 18 MR. WILLE: Your Honor, no redirect for Dr.  
:08:50 19 Redan.  
:08:51 20 THE COURT: Dr. Redan, you are excused.  
:08:53 21 (Witness excused.)  
:09:08 22 MR. WILLE: Your Honor, Lexion recalls Ms.  
:09:11 23 Shelly Amann.  
:09:14 24 THE COURT: Come on up.  
:08:35 25 ... SHELLY AMANN, having been

Amann - direct

:08:36 1 previously duly sworn as a witness, was examined and  
:08:38 2 testified further as follows ...

:08:47 3 THE COURT: Dr. Amann, you're still under oath.  
:08:49 4 You may take your seat.

:08:53 5 MR. WILLE: May it please the Court, Your Honor?

:09:00 6 THE COURT: Yes.

:09:00 7 BY MR. WILLE:

:09:01 8 Q. Good afternoon, Ms. Amann.

:09:01 9 A. Good afternoon.

:09:02 10 Q. I'd like Mr. Barnes to put up on the screen Lexion  
:09:06 11 Exhibit 879.

:09:19 12 All right. Can you see that, Ms. Amann?

:09:22 13 A. Yes.

:09:22 14 Q. Okay. What is Lexion Exhibit 879?

:09:25 15 A. I believe that's a cost justification that SurgiQuest  
:09:31 16 uses.

:09:32 17 Q. Okay.

:09:32 18 A. In the field.

:09:33 19 Q. When did you first see Exhibit 879?

:09:35 20 A. I think I saw it around the fall of 2015 through a few  
:09:43 21 reps in the field.

:09:44 22 Q. Okay. How did Lexion get a copy of this document?

:09:46 23 A. One of the ORs had sent it to one of our  
:09:51 24 representatives originally. I'm not quite sure who it was,  
:09:54 25 but it came from a few people, but it was -- it was a

Amann - cross

:09:58 1 hospital that sent it to one of our reps.

:10:00 2 Q. All right. And had you had discussions with Lexion  
:10:03 3 sales reps about this document since that time?

:10:06 4 A. Yes, because we've seen it in 2016, and I think even  
:10:13 5 as of late, just seeing it from different hospitals that  
:10:17 6 have used it for their cost justification for AirSeal.

:10:21 7 Q. Okay. Let us go to what I believe is slide number 10  
:10:25 8 of the presentation. And if we can zoom in, Mr. Barnes,  
:10:32 9 please, on the top of the slide.

:10:34 10 The title of the slide says, "The AirSeal System  
:10:38 11 eliminates the use of ancillary technologies."

:10:41 12 Did I read that correctly?

:10:42 13 A. Yes.

:10:42 14 Q. All right. And is one of the technologies listed CO2  
:10:46 15 warmers and humidifiers?

:10:47 16 A. Yes.

:10:48 17 MR. WILLE: No further questions.

:10:49 18 THE COURT: Cross.

:10:50 19 MR. RYAN: Thank you, you. Yes.

:10:51 20 CROSS-EXAMINATION

:10:52 21 BY MR. RYAN:

:10:53 22 Q. Ms. Amann -- I'm sorry.

:10:55 23 MR. RYAN: Mr. Splansky, if you would, put up  
:10:58 24 Page 3. Actually, let's stay on the first page of 879.

:11:02 25 BY MR. RYAN:

Amann - cross

:11:17 1 Q. The title of the document is AirSeal Clinical  
:11:20 2 Analysis; isn't that correct?

:11:23 3 A. Yes.

:11:23 4 Q. And in this document there's a series of improvements  
:11:29 5 that patients have been benefiting from as a result of using  
:11:33 6 the AirSeal device; isn't that correct?

:11:35 7 A. I'm not sure.

:11:37 8 MR. RYAN: Would you turn to Page 3, Mr.  
:11:41 9 Splanski.

:11:44 10 BY MR. RYAN:

:11:45 11 Q. Do you understand that at least in this study, Kaiser  
:11:48 12 West, the incidence of shoulder pain went down 90 percent  
:11:53 13 with the use of the AirSeal device?

:11:54 14 A. That's what it states.

:11:56 15 Q. And you see that with respect to shoulder pain  
:12:00 16 severity, it went down 9.7 percent with the use of the  
:12:02 17 AirSeal device?

:12:03 18 Do you see that?

:12:06 19 A. That's what that says.

:12:07 20 Q. Then there's the Kavoussi study, where it says AirSeal  
:12:11 21 reduces CO2 absorption.

:12:13 22 Do you see that?

:12:14 23 A. Yes.

:12:14 24 Q. And then the Benifla study in Paris, France. AirSeal  
:12:21 25 reduces shoulder pain at all time points.



Amann - cross

:12:23 1 Do you see that?

:12:24 2 A. I see that.

:12:26 3 Q. And then the Ramshaw Ventral Hernia Study, where the  
:12:33 4 conclusion was that AirSeal, 61 percent of the patients  
:12:35 5 experience no pain in the PACU. Do you see that? That's  
:12:41 6 right on this document? And that 39 percent of the patients  
:12:43 7 were managed as outpatients; is that correct?

:12:45 8 A. I'm not familiar with how they ran the study, what  
:12:51 9 parameters they measured.

:12:52 10 Q. But you were familiar with the heat and humidification  
:12:54 11 section, is that right, that you testified to a minute  
:12:56 12 ago?

:12:57 13 A. I'm familiar with the cost justification that they've  
:12:59 14 used in this clinical analysis.

:13:02 15 Q. Well, let's talk about the end. There was a  
:13:06 16 comparison of traditional insufflators to the AirSeal  
:13:10 17 insufflator, isn't that right, and that traditional  
:13:13 18 insufflators had a 15.7 percent of patients experiencing no  
:13:18 19 pain, is that right, in this study?

:13:20 20 A. Yes.

:13:20 21 Q. Not quite as good as the 61 percent experienced by the  
:13:24 22 AirSeal; isn't that right?

:13:25 23 A. Again, I'm not familiar with what they used.

:13:29 24 Q. Would you turn to the next page, Mr. Splanski.

:13:36 25 You understand that the evidence mounting

Amann - cross

:13:38 1 regarding the use of the AirSeal device was that there was a  
:13:42 2 significant reduction in the amount of time in the PACU  
:13:48 3 using the AirSeal?

:13:49 4 A. Can you state the question again?

:13:52 5 Q. Sure. There's a study here, the Ramshaw Ventral  
:13:55 6 Hernia Study, PACU Time Study. Do you see that? What's a  
:14:00 7 PACU? Do you know what a PACU is?

:14:03 8 A. Yes. Post-operative Care Unit.

:14:06 9 Q. So what happened with the use of the AirSeal System,  
:14:09 10 there was a 42 percent reduction in the patient's time in  
:14:12 11 the PACU, isn't that right, based on this study?

:14:15 12 A. That's what is stated in this document.

:14:21 13 Q. And in Florida Hospital Celebration, that's Dr.  
:14:26 14 Redan's hospital; isn't that correct? That's his hospital?  
:14:28 15 Yes?

:14:28 16 A. Yes.

:14:29 17 Q. And the surgeon there determined there was a  
:14:32 18 40-percent reduction in time spent in the PACU by using the  
:14:36 19 AirSeal System; isn't that right?

:14:39 20 A. I'm not sure what they determined. That's what is in  
:14:42 21 the AirSeal document.

:14:43 22 Q. And then the amount of morphine used on patients was  
:14:49 23 reduced according to this study when the AirSeal System was  
:14:54 24 used; isn't that correct?

:14:55 25 A. No, that's not correct.

Amann - cross

:14:57 1 Q. So it said pre-AirSeal adoption morphine use, 9.8  
:15:03 2 equivalents, and then post AirSeal use. Do you see that, a  
:15:07 3 62 percent reduction?

:15:08 4 A. I see it in this document that AirSeal is used to sell  
:15:12 5 their unit. I'm not sure if it's -- if those are actual  
:15:16 6 numbers from a study, how it's measured, where it was  
:15:19 7 measured.

:15:20 8 Q. You didn't go back and look; right?

:15:21 9 A. Not to this study, no.

:15:23 10 Q. You just came in and testified about one thing, heat  
:15:26 11 and humidity?

:15:27 12 A. No. I looked at these studies before summer, even  
:15:29 13 were published, yet they're not -- they're not in  
:15:33 14 peer-reviewed journals.

:15:33 15 Q. That's right. The evidence is mounting so much about  
:15:36 16 the AirSeal device, the benefits, that they have not even  
:15:38 17 made their way into peer-reviewed studies yet; isn't that  
:15:41 18 correct?

:15:41 19 A. What's the question?

:15:47 20 Q. There's so much evidence mounting about the benefits  
:15:49 21 recently, about the benefits of the AirSeal System, they  
:15:53 22 have not even had a chance to make their way into  
:15:56 23 peer-reviewed articles yet; isn't that correct?

:15:58 24 A. I don't think that's correct.

:15:59 25 MR. RYAN: Would you turn to Page 7, Mr.

Amann - cross

:16:01 1 **Splanski.**

:16:05 2 **BY MR. RYAN:**

:16:11 3 Q. HCAHPS, do you know what that is?

:16:14 4 A. Yes.

:16:15 5 Q. What is it?

:16:15 6 A. It's a measurement for patients coming out of the --  
:16:20 7 it's a new measurement actually for healthcare that patients  
:16:24 8 are being surveyed after their procedures to determine what  
:16:26 9 the benefits have been.

:16:28 10 Q. And the AirSeal low impact program appears to be,  
:16:32 11 according to this, improving patient outcome, doesn't it?

:16:36 12 A. That's what their document says.

:16:38 13 Q. Yes. There's a reduction of post-operative  
:16:42 14 discomfort; is that right? Is that right?

:16:45 15 A. That's what the document says.

:16:46 16 Q. And there's a reduction in PACU stay; is that right?

:16:50 17 A. I'm not sure where it's coming from.

:16:52 18 Q. There's a reduction in length of hospital stay; is  
:16:55 19 that correct? Is that right?

:16:57 20 A. That's what their document says.

:16:59 21 Q. And a reduction in overall recovery time; isn't that  
:17:01 22 correct?

:17:01 23 A. That's what the documents say.

:17:08 24 **MR. RYAN: Turn to the next page, Mr. Splansky.**

:17:10 25 **BY MR. RYAN:**

Amann - cross

:17:11 1 Q. Now, here, Ms. Amann, again, you see these studies  
:17:14 2 referenced. AirSeal reduced operative time by 21 minutes in  
:17:18 3 the Kavoussi study.

:17:18 4 Do you see that? Do you see that?

:17:21 5 A. Yes.

:17:22 6 Q. And you see that in the Needleman Study, AirSeal  
:17:26 7 reduced operative time by 12 minutes, 13 percent reduction;  
:17:30 8 is that correct?

:17:32 9 A. Reduced operative time, yes.

:17:33 10 Q. That's a benefit to the patient. If, in fact,  
:17:35 11 operative time is being reduced, that's a good thing for the  
:17:38 12 patient, isn't it?

:17:39 13 A. It can be. It depends what products are used.

:17:43 14 Q. Independent of what products are used, isn't it a good  
:17:46 15 thing for the patient to be operated for a shorter period of  
:17:51 16 time than a longer period of time?

:17:52 17 A. Shorter if all -- if nothing is missed and all things  
:17:58 18 are considered and looked at.

:18:01 19 Q. And what was being experienced as well is that the  
:18:04 20 surgeons were able to do more surgeries by using the AirSeal  
:18:07 21 System; isn't that correct, Ms. Amann?

:18:09 22 A. I am not sure about that.

:18:10 23 Q. In fact, this is Vip Patel. Right? Do you know who  
:18:16 24 that is?

:18:17 25 A. I think Dr. Redan testified about Vip Patel.

Amann - cross

:18:20 1 Q. He runs the Robotic Institute at Dr. Redan's hospital,  
:18:25 2 doesn't he, doesn't he? Doesn't he?

:18:28 3 A. I think Dr. Redan mentioned some major complications  
:18:31 4 that Dr. Patel has after prostatectomy procedures, but --

:18:37 5 MR. RYAN: Your Honor, may I?

:18:38 6 THE COURT: Ladies and gentlemen, please  
:18:40 7 disregard that comment. It was not responsive to Mr. Ryan's  
:18:44 8 question.

:18:44 9 BY MR. RYAN:

:18:44 10 Q. Isn't it true that Mr. Patel is one of the busiest  
:18:49 11 urologists in the world; isn't that correct?

:18:51 12 A. That's what it says right there.

:18:52 13 Q. And the benefit of AirSeal is the hospital can drive  
:18:56 14 more surgical procedures; isn't that correct? They can help  
:18:59 15 more people; isn't that right? That's what that said; is  
:19:06 16 that right?

:19:06 17 A. That's what they are saying.

:19:07 18 Q. And that means they can drive more revenue for the  
:19:10 19 hospital; isn't that correct? Isn't that what they are  
:19:14 20 saying?

:19:15 21 A. I'm not quite sure what they are saying.

:19:19 22 Q. And if you could make more money for the hospital,  
:19:21 23 the hospital can buy more life-saving products; is that  
:19:24 24 correct?

:19:25 25 A. If you -- yes. Revenue allows you to buy, to buy

Amann - cross

:19:32 1 life-saving equipment or any kind of equipment.

:19:34 2 Q. You can buy more medication; isn't that correct?

:19:39 3 A. True.

:19:42 4 Q. You can buy all the things necessary to save patients'  
:19:46 5 lives with money; isn't that right?

:19:48 6 A. Correct.

:19:51 7 Q. And the AirSeal System is what is allowing surgeons to  
:19:55 8 do that, according to this; isn't that correct?

:19:58 9 A. What was your question?

:20:03 10 Q. Do you know who Dr. Caceres is, Aileen Caceres, do you  
:20:11 11 know who that is?

:20:11 12 A. I have not met Dr. Caceres.

:20:14 13 Q. Tell the jury where Dr. Caceres works.

:20:15 14 A. She works out of Florida Hospital. Celebration, I  
:20:19 15 believe. That's one of the places she works.

:20:21 16 Q. That's Dr. Redan's hospital; is that right?

:20:23 17 A. Yes.

:20:24 18 Q. Do you understand that Dr. Vip Patel and Dr. Aileen  
:20:32 19 Caceres were reporting into SurgiQuest all of the benefits  
:20:37 20 that were being derived by using the AirSeal System to be  
:20:41 21 able to do more surgical procedures?

:20:43 22 Do you understand that?

:20:44 23 A. I don't know -- I don't know how they got their data.  
:20:49 24 That's what it says.

:20:51 25 Q. Did you ask them? Forgive me.

Amann - cross

:20:53 1 A. I don't know if they were -- if it was fed from them  
:20:57 2 specifically.

:20:58 3 Q. You don't know. When did you first receive this  
:21:01 4 again? The fall of 2015?

:21:02 5 A. Yes.

:21:03 6 Q. Is that what you said?

:21:03 7 A. Yes.

:21:04 8 Q. You asked Dr. Redan to ask his colleagues. Is this  
:21:07 9 true?

:21:08 10 A. We've discussed it.

:21:10 11 Q. Did you ask him to ask his colleagues --

:21:12 12 A. I didn't ask him if they fed them this information.

:21:19 13 Q. Wouldn't you agree if the AirSeal System is a  
:21:23 14 life-saving system allowing surgeons to do more procedures,  
:21:26 15 that that would be a good thing for surgeons to choose it?

:21:29 16 A. Is it life-saving?

:21:35 17 Q. And if it were, and if surgeons could do more  
:21:37 18 procedures, wouldn't it be a good thing for surgeons to use  
:21:42 19 that system?

:21:42 20 A. One, if it didn't cause additional complications.

:21:47 21 Q. And we could leave that determination to Dr. Vip Patel  
:21:51 22 and Dr. Aileen Caceres; isn't that correct?

:21:54 23 A. Doctors are always able to make their own decisions as  
:21:58 24 long as the information that they are receiving is truthful  
:22:01 25 and accurate.



Amann - cross

:22:02 1 Q. And they don't have to rely on what you say or what  
:22:05 2 Mr. Spearman says doctors should use; isn't that correct?

:22:08 3 A. No, they don't. They need to rely on truthful  
:22:12 4 information though.

:22:13 5 Q. And of all of the things you mentioned to the jury  
:22:15 6 today about this document, more surgical procedures done,  
:22:22 7 less surgical pain, better outcomes, the one thing you  
:22:28 8 come in to talk about was heat and humidity; isn't that  
:22:30 9 correct?

:22:30 10 A. That's the one thing that we requested they remove  
:22:33 11 from their documentation.

:22:34 12 MR. RYAN: Thank you very much.

:22:36 13 THE COURT: Mr. Wille?

:22:37 14 MR. WILLE: No redirect, Your Honor.

:22:38 15 THE COURT: Thank you, Ms. Amann. Please be  
:22:40 16 careful.

:22:41 17 (Witness excused.)

:22:44 18 MR. REILLY: Your Honor, Lexion calls Sarah  
:22:48 19 Butler.

:22:48 20 THE COURT: All right.

:23:04 21 ... SARAH BUTLER, having been duly sworn  
:23:12 22 as a witness, was examined and testified as  
:23:14 23 follows ...

:24:17 24 DIRECT EXAMINATION

:24:18 25 BY MR. REILLY:

Butler - direct

:24:19 1 Q. Would you please introduce yourself to the Court and  
:24:25 2 the jury?

:24:26 3 A. Yes. My name is Sarah Butler.

:24:28 4 Q. Are you here today to offer your opinions on Dr.  
:24:31 5 Scott's survey?

:24:32 6 A. Yes.

:24:32 7 Q. What is your connection with this dispute between  
:24:34 8 Lexion and SurgiQuest?

:24:36 9 A. I was asked by Lexion's counsel to review the survey  
:24:39 10 conducted by Dr. Scott.

:24:41 11 Q. Were you able to do that?

:24:42 12 A. Yes.

:24:42 13 Q. What did you do to reach your opinions? What did you  
:24:49 14 review?

:24:49 15 A. I reviewed her report. I reviewed her survey  
:24:53 16 instrument. The questions that were asked. I looked at her  
:24:56 17 survey data. And I reviewed some of the background material  
:25:01 18 and company websites and deposition testimony in the matter.

:25:05 19 Q. And did you form any opinions regarding the Scott  
:25:08 20 survey?

:25:08 21 A. Yes.

:25:09 22 Q. Did you prepare a report stating your opinions  
:25:11 23 regarding the Scott survey?

:25:12 24 A. I did.

:25:13 25 Q. There is a binder in front of you, Ms. Butler. Does

Butler - direct

:25:16 1 that contain your report?

:25:17 2 A. Yes.

:25:17 3 Q. Before we get to your opinions I want to talk to you  
:25:22 4 about your qualifications to testify as an expert.

:25:25 5 Would you please start by telling us a little  
:25:27 6 bit about where you went to school?

:25:29 7 A. I went to undergraduate at Wellesley College. And  
:25:32 8 then I have a Master's degree from Trinity College in  
:25:36 9 Dublin, Ireland. And then I also have a Master's degree  
:25:40 10 from Temple University. And my Master's degree is in what's  
:25:44 11 called field club applied sociology.

:25:46 12 Q. What is applied sociology?

:25:49 13 A. Sociology is the study of the way people react in the  
:25:51 14 world. And applied simply means the mathematics part of it.  
:25:57 15 So I focused on surveys and statistics.

:25:59 16 Q. How does your degree in sociology relate to consumer  
:26:04 17 survey research?

:26:05 18 A. A big part of the graduate training in an applied  
:26:08 19 program is learning how to both collect data and also  
:26:13 20 analyze data, including surveys and statistical data.

:26:18 21 Q. Thank you. Would you tell us a little bit briefly  
:26:20 22 about your professional work history?

:26:22 23 A. Sure. As a graduate student at Temple University I  
:26:26 24 began working for my current company, NERO is a consulting  
:26:33 25 firm, we do quantitative type analyses, more applied. We

Butler - direct

:26:37 1 have people who are economists like Dr. Ugone.

:26:40 2 We have financial people and people like myself  
:26:43 3 who are survey research people and statisticians.

:26:45 4 Q. What is your current job?

:26:47 5 A. So I am a managing director, which means I have my own  
:26:50 6 research group, I am also the head of our San Francisco  
:26:53 7 office. I am our pro bono coordinator. I have worked for  
:27:00 8 the company for a long time.

:27:01 9 Q. What type of clients have you done work for?

:27:03 10 A. A broad range of clients. So we worked for big  
:27:07 11 companies, small companies. I have worked for the FTC, the  
:27:11 12 Federal Trade Commission, the Department of Justice, I have  
:27:14 13 worked for the Attorney General of Washington State,  
:27:17 14 California.

:27:17 15 Q. I believe you mentioned that you had done some work  
:27:20 16 apart from NERA. Is that correct?

:27:22 17 A. Yes.

:27:22 18 Q. Tell us a little bit about that?

:27:24 19 A. I have kind of taken a sabbatical from my current  
:27:27 20 company twice, and for a while I worked for a market  
:27:32 21 research firm that primarily worked with pharmaceutical  
:27:35 22 companies and medical device companies. So I have reviewed  
:27:38 23 doctors and patients, ran focus groups. I also took some  
:27:44 24 time out to do some consulting on my own and also some  
:27:46 25 academic teaching.

Butler - direct

:27:50 1 Q. And have you published any writings or papers or done  
:27:53 2 any presentations in the course of your career?

:27:55 3 A. I have.

:27:56 4 Q. Tell us a little bit about those?

:27:58 5 A. Sure. So I often give presentations to folks like  
:28:03 6 yourselves, lawyers, about how best to do surveys for court  
:28:07 7 and what kind of standards courts are looking for when  
:28:10 8 designing appropriate survey research.

:28:12 9 But I have also written some articles that are  
:28:15 10 in peer-reviewed journals. So I recently published an  
:28:19 11 article with a colleague of mine about using survey  
:28:23 12 techniques to evaluate the value of privacy, private,  
:28:28 13 personal information.

:28:31 14 Q. Does any of your work in research relate to medical  
:28:34 15 devices?

:28:35 16 A. Yes.

:28:35 17 Q. How long have you been doing consumer research?

:28:38 18 A. I have been doing consumer research for about 20  
:28:41 19 years.

:28:42 20 MR. REILLY: Your Honor, we offer Ms. Butler as  
:28:44 21 an expert in the field of survey search.

:28:46 22 MR. RYAN: No objection, Your Honor.

:28:47 23 THE COURT: Ms. Butler is accepted as an expert  
:28:50 24 in that area.

:28:51 25 THE COURT: Let me see counsel off the record,

Butler - direct

1 just briefly.

2 (Sidebar conference not reported)

3 THE COURT: Ladies and gentlemen, this is our  
4 last witness in the case. I am going to detain you just a  
5 bit longer, maybe 15 minutes beyond the 4:30 hour, in the  
6 interests of time and trying to get our jury instructions  
7 ready.

8 We will still be here after you leave. And  
9 hopefully tomorrow morning, I will get to give you your  
10 instructions and our closing speeches.

11 BY MR. REILLY:

12 Q. Ms. Butler, before we heard Dr. Scott's testimony, she  
13 talked about standards that are followed in preparing  
14 surveys. Correct? Do you recall that?

15 A. Yes.

16 Q. Is there an overarching principle or standard that  
17 should be followed when conducting consumer research  
18 surveys?

19 A. Sure. So, you know, I think Dr. Scott named some of  
20 the kind of specificities in terms of finding the right  
21 population, analyzing the data properly.

22 But kind of the primary thing, of course, one  
23 wants to do in a survey is what we call replicate  
24 marketplace conditions.

25 Q. And in your judgment or opinion, did Dr. Scott achieve

Butler - direct

:30:26 1 that?

:30:26 2 A. No.

:30:27 3 Q. Do you say that through her survey?

:30:29 4 A. No.

:30:29 5 Q. Why do you say that?

:30:31 6 A. As I think you heard here, the sales process here, or  
:30:34 7 the process by which surgeons and other relevant individuals  
:30:39 8 receive information about medical devices and products is  
:30:42 9 kind of an interactive and somewhat extensive process.

:30:47 10 So a survey which simply shows a chart and  
:30:50 11 doesn't show doctors to look at any other information isn't  
:30:55 12 really replicating that process.

:30:56 13 Q. Are there ways that could have been approached or done  
:30:59 14 to do that?

:31:00 15 A. Yes. So with our iPhones, we can film people. So you  
:31:05 16 could film somebody giving a sales pitch. You could write  
:31:09 17 text that might replicate what somebody might say when  
:31:15 18 presenting a chart such as this.

:31:17 19 Or you could even set up kind of the scenario or  
:31:20 20 the hypothetical that you want your survey respondents to  
:31:23 21 imagine themselves in, which is just a longer introduction  
:31:27 22 that explains kind of the mindset you would like your  
:31:30 23 respondent to be in.

:31:30 24 Q. And did you also consider the control that was used in  
:31:35 25 the survey?

Butler - direct

:31:35 1 A. Yes.

:31:36 2 Q. And do you have any opinions about the control?

:31:41 3 A. So as Dr. Scott pointed out, she did a test and a  
:31:44 4 control. So the test was the chart, the Lexion chart, and  
:31:47 5 she has a control that has the bars that are exactly  
:31:52 6 equivalent. And the purpose of that control, as she  
:31:56 7 described it, was to try to assess maybe reactions of her  
:32:03 8 survey respondents that weren't due to the differences shown  
:32:05 9 in the chart but were due to something else. But, of  
:32:09 10 course, that control chart shows no difference.

:32:14 11 To the extent that people are concerned about  
:32:15 12 any types of differences, she can't measure that.

:32:19 13 It's not really a sufficient control.

:32:22 14 Q. And does that impact the reliability of the survey  
:32:26 15 results?

:32:27 16 A. Yes.

:32:28 17 Q. How?

:32:28 18 A. What it means is in the test conditions, you can't  
:32:30 19 tell how many people are just reacting to the fact that we  
:32:34 20 have given them a chart that shows some kind of difference.  
:32:38 21 A chart that has some difference would probably suggest to  
:32:41 22 most people, hey, this is something I should pay attention  
:32:46 23 to.

:32:46 24 Q. In your judgment, is the Scott survey something that  
:32:49 25 is reliable?



Butler - cross

:32:51 1 A. No. I think for a couple of reasons, both the  
:32:54 2 marketplace, she also hasn't surveyed some of the people  
:32:58 3 that are important decision-makers in this process, they  
:33:01 4 aren't part of the survey. And the survey doesn't really  
:33:05 5 have an appropriate control.

:33:07 6 MR. REILLY: No further questions at this time.  
:33:09 7 Pass the witness, Your Honor.

:33:10 8 THE COURT: Mr. Ryan.

:33:11 9 CROSS-EXAMINATION

:33:11 10 BY MR. RYAN:

:33:12 11 Q. Just a few questions. It's Ms. Butler. Is that  
:33:27 12 correct?

:33:27 13 A. Yes.

:33:28 14 Q. How many surveys have you done in your career?

:33:33 15 A. Upwards of a hundred for sure.

:33:34 16 Q. How many of those surveys were accepted by Federal  
:33:40 17 District Courts, if you know?

:33:44 18 A. Well, an easier way to answer your question, because  
:33:48 19 sometimes cases settle and they don't go all the way to  
:33:51 20 court, I have not had a survey excluded.

:33:54 21 Q. Thank you. And you didn't do a survey in this case,  
:33:58 22 did you?

:33:59 23 A. No.

:33:59 24 MR. RYAN: Thank you very much.

:34:01 25 THE COURT: Mr. Reilly, anything?

:34:03 1 MR. REILLY: No redirect.

:34:03 2 (Witness excused.)

:34:08 3 THE COURT: Mr. Wille.

:34:09 4 MR. WILLE: Your Honor, Lexion rests.

:34:13 5 THE COURT: Ladies and gentlemen, as predicted,  
:34:15 6 we have come to the end of the evidence in the case. I want  
:34:17 7 you to remember my early instructions at the very beginning  
:34:20 8 of the case. We will get you your final instructions in the  
:34:24 9 morning and see you at 9:00.

:34:28 10 (Jury leaves courtroom at 4:34 p.m.)

:34:45 11 THE COURT: All right. Others can be seated.  
:34:48 12 Do we have any another iteration?

:34:51 13 MR. RYAN: We have made a lot of progress. We  
:34:54 14 didn't have a chance to do an iteration. We can -- I guess  
:34:57 15 we can ask the Court what you think the most efficient way  
:35:00 16 to do it is. There are sections we have absolutely  
:35:03 17 agreed-upon language now.

:35:04 18 THE COURT: Let's take a bio break, then you can  
:35:12 19 tell me.

:35:13 20 MR. WILLE: Your Honor, I think both sides would  
:35:15 21 like to renew their motions for the record.

:35:18 22 THE COURT: I will reserve. I can promise you,  
:35:21 23 that's what I would have done, not having seen the motions,  
:35:24 24 I am sure they would have been very erudite and  
:35:29 25 overwhelmingly convincing. But not in this case.

:35:35 1 (Recess taken.)

:42:56 2 THE COURT: So here we go. Here's the way this  
:43:33 3 is going to work. I'm going to ask that you identify the  
:43:41 4 areas of agreement. Okay. Let's start there. Start with  
:43:47 5 good news.

:43:48 6 MR. RYAN: Good.

:43:50 7 MR. REILLY: Your Honor, I think I can start  
:43:52 8 with the first on Page 16, element 1, false or misleading  
:43:55 9 statements.

:43:59 10 THE COURT: Okay.

:44:00 11 MR. REILLY: Under literally false, the last  
:44:03 12 sentence of that paragraph. What we've agreed to change  
:44:07 13 that language to, this means that the statement when read in  
:44:13 14 context is ambiguous or susceptible of more than one  
:44:18 15 reasonable meaning. It may not be found to be literally  
:44:23 16 false.

:44:24 17 THE COURT: Okay. All right. That's good.

:44:41 18 Thank you.

:44:48 19 MR. RYAN: Page 18, Your Honor. The bracketed  
:44:50 20 language beginning, once in plaintiff's. It would be once a  
:44:53 21 party proves literal falsity of an advertising claim, you  
:44:59 22 may presume that all other aspects or elements of liability  
:45:04 23 of that claim have been established, and you may find the  
:45:09 24 other party liable for false advertising, but for the  
:45:14 25 purpose of establishing any amount of damage, you must

1 determine what harm, if any, was caused by such false  
2 advertising.

3 THE COURT: Okay. Let's go back to that. So  
4 the language after advertising all comes out. Right?  
5 Beginning with --

6 MR. REILLY: No. I am sorry, your Honor.

7 THE COURT: Okay.

8 MR. REILLY: Maybe we had a disagreement,  
9 Mr. Ryan. I had thought that we would keep in that language  
10 without considering. The way I had it was, a party, once a  
11 party proves literal falsity of an advertising claim, you  
12 may presume that all other aspects or elements of liability  
13 for false, for a false advertising claim have been  
14 established, and you may find the other party liable for  
15 false advertising without considering the advertiser's  
16 claims impact on the purchasers, but for the purposes of  
17 establishing damages, you must -- I'm sorry, your Honor. I  
18 am having trouble reading my own writing. But that's where  
19 we left off. I think Mr. Ryan had the appropriate language  
20 at that point.

21 MR. RYAN: You have to look at --

22 THE COURT: I don't want to have an argument. I  
23 want to know what points you agree on.

24 MR. RYAN: We don't agree you're going to remove  
25 without considering --

:46:34 1 THE COURT: So then we don't have an agreement.

:46:35 2 MR. RYAN: I thought we did, Your Honor. I

:46:36 3 guess not.

:46:37 4 THE COURT: Do you want to massage this a little

:46:38 5 bit and see --

:46:43 6 MR. RYAN: I think --

:46:43 7 THE COURT: No, right now.

:46:49 8 Let me help you. It says, without considering

:47:20 9 the advertiser's claims, without considering the

:47:25 10 advertiser's claims -- there's a typo, I guess -- impact on

:47:31 11 the purchasers. That's not true. Okay. That's our

:47:34 12 understanding of the law. Materiality has to be

:47:38 13 contemplated. Okay?

:47:43 14 MR. REILLY: Your Honor, may I?

:47:44 15 THE COURT: Yes. I don't know if that is where

:47:49 16 the problem is.

:47:50 17 MR. REILLY: No. It's the impact on the

:47:51 18 advertising purchaser. I think that's going more to the

:47:53 19 confusion element of the impact and there's materiality

:47:59 20 there, because this language I was taking from the District

:48:02 21 Court of Delaware case.

:48:03 22 THE COURT: Judge Robinson?

:48:04 23 MR. REILLY: Where Judge Robinson had found that

:48:07 24 all elements are established if you prove the literal

:48:09 25 falsity.

:48:10 1 THE COURT: She didn't cite the case law for  
:48:12 2 that proposition.

:48:13 3 MR. REILLY: She cited to Castrol, I believe,  
:48:16 4 Your Honor, and that case. I will say, there were multiple  
:48:21 5 iterations of opinions because the defendant kept arguing  
:48:23 6 over the point.

:48:24 7 THE COURT: Yes. And I think we found no case  
:48:27 8 reference for that proposition.

:48:30 9 I just interrupted. Were you --

:48:32 10 MR. REILLY: No, no. It's helpful, Your Honor,  
:48:34 11 because that does allay an issue. And if you believe that  
:48:38 12 that language needs to be removed, then we could probably go  
:48:41 13 back and follow up with where Mr. Ryan had left.

:48:44 14 THE COURT: Why don't you go ahead.

:48:47 15 MR. REILLY: But I do believe that's exactly  
:48:49 16 what the Judge had held in that case.

:48:50 17 THE COURT: Do you have the cases she cited?

:48:53 18 MR. WILLE: I do, Your Honor.

:48:53 19 THE COURT: I mean, do you have her opinion?

:48:55 20 MR. REILLY: Yes.

:48:56 21 THE COURT: The most recent iteration? Just  
:48:58 22 point to the passage.

:48:59 23 MR. REILLY: Sure. May I approach, Your Honor?

:49:26 24 THE COURT: Sure. Right here?

:49:34 25 MR. REILLY: Yes, sir.

:49:46 1 THE COURT: Yes. I think back to -- there's  
:49:49 2 no case cite. There's no authority cited. Section 43(a),  
:49:53 3 but --

:49:54 4 MR. REILLY: Understood, your Honor. Above  
:49:55 5 that, she cites to Castrol, which talks about the  
:49:58 6 presumption, I believe.

:50:21 7 THE COURT: Don't you need to still -- and Judge  
:50:25 8 Robinson's opinion, I think you can read in into what she's  
:50:29 9 saying, but you still have to have causation.

:50:32 10 MR. REILLY: Causation on the point of injury  
:50:35 11 and damage -- on damage, yes, Your Honor. But what was at  
:50:40 12 issue in that case, the defendant kept arguing, saying the  
:50:44 13 presumption doesn't go to materiality, and in one of the  
:50:46 14 earlier opinions, the Judge said, no. I disagree again with  
:50:51 15 you, counsel and defense. Materiality is presumed, and you  
:50:54 16 wouldn't get to your presumption of confusion at the  
:50:57 17 consumer level unless you walked through those steps to get  
:51:00 18 there, so it has to be implied in there that it also  
:51:03 19 includes materiality, Your Honor.

:51:12 20 THE COURT: What's your view on that, Mr. Ryan?

:51:14 21 MR. RYAN: Your Honor, here is the concern.  
:51:15 22 These are all pre-eBay, pre-Ferring, and pre-Group ASEP  
:51:22 23 cases, where the Third Circuit, in the context of a literal  
:51:27 24 falsity case, was analyzing what type of presumptions are  
:51:31 25 appropriate or not appropriate.

1           The Court concluded, the Court was catching up  
2 with what had happened, the Supreme Court with patent law to  
3 the trademark context, and this was actually a false  
4 advertising case.

5           MR. RYAN: The Court concluded you can't presume  
6 harm. You have got to prove it. In that case, of course,  
7 it happened to be injunctive relief. But nevertheless, I  
8 think post eBay, and the cases that followed, you can't come  
9 up with this presumption anymore. You can't presume harm,  
10 even I think in a literal falsity context, I think you have  
11 to prove it. I think that is particularly important here  
12 because the issue that the jury is going to be asked to  
13 consider is whether or not the deception caused surgeons or  
14 the market to make a decision.

15           MR. REILLY: Your Honor, if I may. The  
16 irreparable harm that Mr. Ryan is referring to is that  
17 irreparable harm. Not injury under the statute.  
18 Irreparable harm for purposes of preliminary injunction or  
19 for permanent injunction is a different animal. It's a step  
20 removed from the liability at the bottom end.

21           They are talking about presumption of  
22 irreparable harm in order to grant relief.

23           This is establishing liability on the claim  
24 itself. We are not talking about materiality in the  
25 context, technically, of political falsity. But we are



1 here, because the presumption applies. And if it applies,  
2 then we don't need to establish the materiality aspect of  
3 it.

4 MR. RYAN: Your Honor --

5 THE COURT: You don't accept the distinction.

6 MR. RYAN: I think it's an important  
7 distinction. The problem is we think it goes too far. The  
8 presumption he is making is that they have established all  
9 elements of a Lanham Act claim and that is not what the law  
10 can be, whether at the end of the case, whether it be the  
11 Court considering an 1125(a) claim in the context of a case  
12 involving false advertising or a trademark context.

13 There has to be a link between the conduct and  
14 the harm being alleged by the party, by the plaintiff.

15 The presumption that I think is being asked for  
16 here skips that, the limiting step.

17 Essentially, what he would like is a ruling --  
18 excuse me, Your Honor, an instruction to the jury that there  
19 is a foregone conclusion that a remedy should be provided  
20 for this conduct. We don't agree with that. We don't  
21 believe that's the law.

22 MR. REILLY: As Castro and many of the Third  
23 Circuit cases say, that if you have literal falsity,  
24 consumer confusion is presumed. That is the harm.

25 Let's move to the next step. Let's go to

1 injunctive relief or damages.

2 THE COURT: You don't agree that Castro and the  
3 circuit are in that space?

4 MR. RYAN: Those are all pre-eBay. They are all  
5 pre-Ferry and all pre Group ASCB, where the Third Circuit  
6 was asked to review a District Court ruling on a finding of  
7 literal falsity.

8 THE COURT: So the circuit has not ruled on this  
9 question.

10 MR. RYAN: I think it's open as to exactly what  
11 the presumption should apply to. I believe what is being  
12 represented by Mr. Reilly is accurately the case law, that  
13 if you have a determination of literal falsity, the courts  
14 are questioning whether or not you need to go through the  
15 entire process of proving all of the elements pre-injury.  
16 That's what those cases are all saying.

17 The problem with that is, I am not sure a  
18 presumption is appropriate after eBay, after Ferry, after  
19 Group ASCB and after the Third Circuit's interpretation of  
20 when a presumption is appropriate for injunctive relief. If  
21 it is not appropriate there, how can it possibly be  
22 appropriate for monetary relief?

23 That is problem, Your Honor.

24 MR. REILLY: I disagree. I think you are  
25 conflating the two. You are conflating damages in with the

1 liability phase of this case.

2 THE COURT: That is the distinction you are not  
3 addressing, Mr. Ryan, that Mr. Reilly is trying to draw.

4 MR. RYAN: We had agreement on whether or not a  
5 presumption applies to purely the liability. I don't think  
6 there is a dispute on that. What he seeks to be drawing is  
7 the next step. There should be a presumption as to the  
8 remedy. What I am saying is as to the remedy --

9 THE COURT: Is that what you are doing?

10 MR. REILLY: No.

11 MR. RYAN: Then it's consistent with what he and  
12 I spoke about.

13 THE COURT: I don't think he is doing that.  
14 Let's hear the language.

15 MR. REILLY: Once plaintiff proves literal  
16 falsity in an advertising claim, you may presume that all  
17 other aspects or elements of liability of a false  
18 advertising claim have been established and you may find the  
19 other party liable for false advertising without considering  
20 the advertising claim's impact on purchasers. But for the  
21 purposes of establishing any amount of damages, you must  
22 find that the plaintiff has been harmed.

23 MR. RYAN: And that harm was caused by such  
24 false advertising.

25 THE COURT: Do you have a problem with that?

:57:11 1 MR. REILLY: No, Your Honor.

:57:12 2 THE COURT: I think that gets it. It would be  
:57:14 3 good if you could break that up a little. That is a long  
:57:18 4 sentence.

:57:18 5 MR. RYAN: One more element, if I may.

:57:21 6 It's simply, it's a rebuttable presumption.

:57:24 7 Either we can build in -- we have already agreed to  
:57:28 8 language.

:57:29 9 MR. REILLY: I don't have an issue.

:57:30 10 MR. RYAN: It is a preference of Your Honor, how  
:57:32 11 you like to treat rebuttable presumptions. Do you like it  
:57:35 12 built into the instruction or do you want a separate line?

:57:37 13 THE COURT: No. My approach to this is where  
:57:40 14 parties can agree, that's better than the Court imposing its  
:57:45 15 preference or its nudge or whatever the case may be. If  
:57:50 16 there is agreement on this point --

:57:52 17 MR. RYAN: We have language.

:57:53 18 THE COURT: And that I am not abdicating my  
:57:56 19 role, and I don't think I am in this instance, to oversee  
:58:00 20 the preparation of accurate instructions. I think counsel  
:58:04 21 have arrived at a reasonable solution.

:58:07 22 MR. RYAN: Do you want me to read that language?

:58:10 23 MR. REILLY: Do you want us to rewrite it and  
:58:13 24 send it in?

:58:14 25 THE COURT: No. Because tomorrow morning, we

1 are going to have collated copies.

2 MR. RYAN: Would you like the language now, or  
3 at least the last portion?

4 THE COURT: Let's make sure we have the whole  
5 thing on the record and there is agreement.

6 MR. RYAN: It would simply follow the  
7 instruction Mr. Reilly read. It would be, the foregoing  
8 does not prove -- we have here the defendant, we have to put  
9 the other party, or however you want to word it, from  
10 offering evidence to rebut political falsity.

11 THE COURT: Mr. Reilly, is that acceptable?

12 MR. REILLY: Yes.

13 MR. RYAN: I guess, to be accurate, if that's  
14 what we do, I guess to be clear for the jury, that would  
15 mean that under a rebuttal scenario, then the jury would  
16 have to go through the exercise of deception, materiality,  
17 but maybe we can do it in a way that would refer them to an  
18 instruction later on.

19 We have to let the jury know what would happen  
20 if the presumption --

21 MR. REILLY: We have addressed that in the next  
22 section, where we get to materiality, it would say, if the  
23 party does not prove an advertising claim is literally  
24 false, it must prove X.

25 MR. RYAN: That makes sense. We can add, or the

1 literal falsity presumption has been rebutted.

2 THE COURT: I don't want there be to be slippage  
3 overnight. Let's read into the record exactly what the  
4 language is going to look like in the final iteration.

5 MR. REILLY: This is what we have so far, Your  
6 Honor.

7 Once a party proves literal falsity of an  
8 advertising claim, you may presume that all other aspects or  
9 elements of liability of a false advertising claim have been  
10 established, and you may find the other party liable for  
11 false advertising without considering the advertising  
12 claim's impact on the purchasers. But for the purposes of  
13 establishing any amount of damages, you must -- I am sorry,  
14 this is where my note dropped off --

15 MR. RYAN: -- you must still determine what  
16 harm, if any, was caused by such false advertising.

17 MR. REILLY: Yes, sir.

18 THE COURT: Agreed.

19 MR. RYAN: Yes.

20 MR. REILLY: Yes.

21 MR. RYAN: The followup would be the rebuttable  
22 presumption language.

23 THE COURT: That is where we are going to  
24 address that.

25 MR. RYAN: This sentence, first, we are in

1 agreement on this. The foregoing does not preclude the  
2 defendant from offering evidence to rebut literal falsity.

3 THE COURT: Mr. Reilly.

4 MR. REILLY: I think that's satisfactory.

5 MR. RYAN: Thank you, Your Honor.

6 THE COURT: I am satisfied.

7 Let's go to the next point of agreement.

8 MR. REILLY: Your Honor, that brings us, I  
9 believe, to the misleading statements. I am at Page 19.  
10 Down at the bottom, there is language in brackets, if you  
11 will, you will see, Page 19, in the case, the relevant  
12 audience for determining consumer deception is where I am  
13 looking, Your Honor. It seems to me this jury is well  
14 schooled in who the players are here and what is at issue.

15 I think the target audience's special knowledge  
16 of a class of product should be considered isn't appropriate  
17 here. That is just going to add another layer.

18 They are the jury here, finders of facts, they  
19 have enough evidence in the record of who saw what in terms  
20 of the advertising at issue.

21 THE COURT: Do you agree?

22 MR. RYAN: No. Here we have --

23 THE COURT: I thought we were going through the  
24 agreed.

25 MR. REILLY: I'm sorry, Your Honor. I jumped

1 out of order.

2 THE COURT: Yes.

3 MR. RYAN: We think there has to be an  
4 instruction regarding the special knowledge of the robotic  
5 surgeons, which is the core market that plaintiff claims was  
6 deceived by the allegations of false advertising. What we  
7 think, however, in this misleading statement section is that  
8 we don't believe that the Court should be instructing the  
9 jury that it should do something as opposed to that it may.  
10 So we think we should soften that language, both at the end  
11 of that one section, a target audience's special knowledge  
12 of a class of products may be considered, and then the  
13 carryover, instead of saying you should, it should be, you  
14 may.

15 We don't believe the jury should be instructed  
16 that affirmatively on this point, Your Honor, and I think  
17 that accounts for Mr. Reilly's point, that the jury can  
18 consider what it wants with respect to target audience.

19 MR. REILLY: Your Honor, if I may?

20 THE COURT: Yes. I'm listening.

21 MR. REILLY: I'm looking down at Diagnostic  
22 versus Amersham, quoted language. It's not binding on the  
23 Court. It says, when determining whether a claim is  
24 literally false, audience sophistication is irrelevant.

25 MR. RYAN: This is misleading. This isn't



1 literal falsity. We don't disagree with that. This is the  
2 misleading section.

3 THE COURT: Which case are you citing to?

4 MR. REILLY: Down underneath the objection on  
5 Page 20, Your Honor. Footnote 46.

6 THE COURT: All right.

7 MR. REILLY: I've also cited, I believe, to  
8 McCarthy.

9 THE COURT: All right. I will say this. In  
10 reading the instructions, I tend to agree with you,  
11 Mr. Reilly, not just this instruction. This seemed to  
12 pervade these instructions. They seem to be argumentative  
13 in places, and one party proselytizing the jury one way and  
14 the other party the other, and that's not the purpose of  
15 jury instructions, and that concerned me, and it's something  
16 I meant to say at the outset. So I don't know where that  
17 leaves us in terms of Amersham.

18 MR. RYAN: It's something honestly, Your Honor,  
19 Mr. Reilly and I discussed.

20 THE COURT: Yes.

21 MR. RYAN: At times the jury instructions were  
22 too assertive in what the expectation was to the jury.

23 THE COURT: Yes.

24 MR. RYAN: And what he and I both worked to do  
25 was to remove the word "should," include the word "may,"

1 allow the jury to make its own assessments.

2 With respect to this specific issue, I just call  
3 the Court's attention to the Sandoz case, where in Sandoz,  
4 even with respect to this medication, doctors,  
5 pediatricians, were perceived to have a higher level of  
6 knowledge than the ordinary consumer.

7 MR. REILLY: Your Honor, but even in this  
8 instance, we've gotten, you know, doctors who are confused  
9 by this issue and their sophistication isn't helping.  
10 So it's not a helpful instruction to the jury to get  
11 something that might be contradictory to what we see in the  
12 record.

13 THE COURT: Yes. I tend to agree with that,  
14 Mr. Ryan. There's a good bit of evidence in this case of  
15 doctor confusion. Don't you agree? You may not agree with  
16 it, but just as objective as you can be about it, there's  
17 doctor confusion evidence on this record.

18 MR. RYAN: And my point is, if that's the  
19 appropriate class, the jury -- of consumer who has  
20 purportedly been deceived, because respectfully, Your Honor,  
21 it's not confusion. The issue is whether or not a surgeon  
22 was deceived in purchasing a product.

23 THE COURT: Well, isn't there an element of  
24 confusion that's asserted to be deceived?

25 MR. RYAN: I don't believe so, Your Honor. I

1 think there's a clear distinction --

2 THE COURT: I don't know if that follows the  
3 logic of that, but it seems to me --

4 MR. REILLY: No. I believe you're on target  
5 there, Your Honor. It's confusion, and the whole Lanham  
6 Act, both sections of the Lanham Act address confusion,  
7 deception or mistake.

8 THE COURT: Yes. So what is your -- your  
9 proposal --

10 MR. REILLY: Strike it.

11 THE COURT: -- is to strike this bracketed  
12 language?

13 MR. REILLY: Is to strike that entire paragraph,  
14 all the way to paragraph 20. I mean all the way to the next  
15 page.

16 MR. RYAN: And ours would be, Your Honor, just  
17 remove the word "should" and include the word "may." We  
18 don't think the word "should" should have been included in  
19 that instruction.

20 THE COURT: Mr. Reilly, do you agree? Do the  
21 parties in your view agree on this identification of the  
22 relevant audience being surgeons and hospitals?

23 MR. REILLY: Well, I think it is a little bit  
24 broader than that, Your Honor. I think it's also the  
25 constituents of who they are arguing with. There are

1 general purchasing organizations that are involved. There's  
2 hospitals. There's hospital coordinators who have an input.  
3 There's these value assessment people.

4 THE COURT: I agree with that and I don't want  
5 this jury to be constrained. If they see the evidence in  
6 that way, they might distill it down to surgeons in  
7 hospitals, but I'm not prepared to handcuff them like  
8 that.

9 MR. RYAN: Your Honor, if that's what we do,  
10 we're not going to know what juror was confused by which  
11 claim and why, and what's really important here is the  
12 target audience that they are claiming they lost sales on  
13 was a surgeon.

14 So respectfully, we think it's worth putting --

15 THE COURT: That's your evaluation of the  
16 evidence, Mr. Ryan.

17 MR. RYAN: Of course, your Honor.

18 THE COURT: Yes.

19 MR. RYAN: But all I'm saying is, that's why we  
20 think an instruction that at least allows for the jury to  
21 consider it with "may" language is appropriate.

22 Your Honor, we understand the Court's point. I  
23 just wanted to make sure you understood why it is we think  
24 it's important.

25 THE COURT: Well, what I'm telling you is, if

1     you're going to even get me to consider the inclusion of any  
2     form of this language, I'm not going to tell this jury that  
3     the relevant audience is constrained or constricted or just  
4     simply surgeons and hospitals.

5             MR. RYAN: We don't mean to suggest that, Your  
6     Honor.

7             THE COURT: Well, that's what you're telling me.

8             MR. RYAN: That's because prior, prior  
9     conversations, we're focusing on surgeons, robotic surgeons.  
10    We have no problem expanding that. And to the extent the  
11    jury concludes --

12            THE COURT: And that leads me to this thought,  
13    that a target audience has special knowledge -- if it's not,  
14    in fact, just surgeons and hospitals, we don't know anything  
15    about it, do we? The special, so-called special knowledge.  
16    I think that that renders that language, if I'm scratching  
17    out certain -- and hospitals, I don't think the next  
18    sentence follows. It doesn't make sense. I'm going to  
19    agree.

20            MR. REILLY: Your Honor, can I give you an easy  
21    one?

22            THE COURT: Give me an easy one.

23            MR. REILLY: One we have an agreement on.

24            THE COURT: Just so the record is clear, I'm  
25    striking the bracketed language at Pages 19 and 20.

:08:05 1 MR. RYAN: Understood.

:08:06 2 THE COURT: All right.

:08:06 3 MR. REILLY: On Page 31, there's this bracketed  
:08:08 4 language, a plaintiff needs to establish is likely to be  
:08:13 5 injured.

:08:13 6 THE COURT: Yes.

:08:14 7 MR. REILLY: We believe in talking to Mr. Ryan  
:08:16 8 and myself that much of that language is covered above  
:08:19 9 in the first paragraph and so it might be viewed as  
:08:21 10 redundant.

:08:22 11 THE COURT: Okay.

:08:24 12 MR. REILLY: So we believe that paragraph which  
:08:26 13 is marked by 83 can come out.

:08:27 14 THE COURT: Okay. Do you agree, Mr. Ryan?

:08:29 15 MR. RYAN: We do. There's another piece to  
:08:31 16 that, but, yes, on that language, we agree.

:08:34 17 THE COURT: The additional piece coming the next  
:08:36 18 page?

:08:37 19 MR. RYAN: Are you going to go ahead? Please.

:08:39 20 MR. REILLY: We've talked about this language  
:08:42 21 relates to damages, and in my judgment and in talking to Mr.  
:08:46 22 Ryan, I think he agrees, it is that really damages don't  
:08:50 23 believe in this part on the liability analysis, and this  
:08:52 24 really should come later when we're talking about damages so  
:08:54 25 we don't confuse the jury.

:08:56 1 THE COURT: Do you agree?

:08:57 2 MR. RYAN: Yes. We would recommend that we cut  
:08:58 3 that language and we insert it later on.

:09:00 4 THE COURT: That's the language beginning with,  
:09:02 5 a plate of seeking monetary languages must link?

:09:06 6 MR. REILLY: Yes.

:09:06 7 MR. RYAN: Yes.

:09:07 8 THE COURT: Let's take that sentence out.

:09:08 9 MR. RYAN: And cross out the however sentence  
:09:10 10 completely, Your Honor.

:09:11 11 THE COURT: However? We're going to cross that  
:09:13 12 out. Mr. Reilly, agreed?

:09:16 13 MR. REILLY: Yes, Your Honor.

:09:16 14 THE COURT: All right. Good. Okay. That's  
:09:19 15 agreed. And this language will reappear.

:09:23 16 MR. REILLY: Yes. We have not plotted that out  
:09:25 17 exactly where it needs to go, Your Honor.

:09:28 18 THE COURT: Okay. Let's keep going.

:09:29 19 MR. REILLY: That sort of pulls me back to the  
:09:31 20 last page where we had an issue or dispute. I'm not sure if  
:09:35 21 there were other points that we're in disagreement, but if  
:09:41 22 Mr. Ryan has his fingerprints.

:09:42 23 THE COURT: Are there any more agreed-upon  
:09:44 24 points?

:09:44 25 MR. RYAN: I think that's it in this section,

1 Your Honor.

2 THE COURT: Well, let's cycle back and go  
3 through the disagreements.

4 MR. REILLY: So the next one we're at is the  
5 language on Page 20, Your Honor. That is captioned,  
6 disclaimers or remote disclosures.

7 THE COURT: Wait a minute. Oh, the caption.  
8 You did say the title. Yes.

9 MR. REILLY: So I would be amenable to removing  
10 the language disclaimers from that instruction here. Mr.  
11 Ryan has a concern or an issue about the requirement for FDA  
12 disclosures that are required in IFUs.

13 Our position is that an IFU technically isn't  
14 really sort of connected. It's very remote from the  
15 advertising claims that are at issue, and we feel that a  
16 jury should understand that when you've got a remote  
17 disclosure or language trying to change the meaning of what  
18 is presented in that advertising, that really shouldn't be  
19 considered. It certainly shouldn't be given the weight that  
20 might otherwise be afforded a proper disclaimer that's right  
21 up there in the advertising.

22 Our thought was to put some instructions so the  
23 jury understands exactly how that might play into this kind  
24 of situation.

25 THE COURT: I tend to agree with that. Mr.



1 Ryan?

2 MR. RYAN: Your Honor, an IFU that is required  
3 pursuant to FDA law in no way, shape or form should be  
4 considered in conjunction with any advertisement. The  
5 document --

6 THE COURT: Where you lose me sometimes, this is  
7 an FYI to you, sometimes, "in no way, shape or form," you  
8 get a little hyperbolic. It's like the boy who called  
9 "Wolf" after while. So if you tone down --

10 MR. RYAN: Your Honor, there is no case where an  
11 IFU is used and even argued as a disclaimer to advertising.  
12 And the IFU stands on its own when it comes to how it  
13 advises or does not advise a user or potential user on a  
14 medical device product.

15 What Mr. Reilly would like to do is link the IFU  
16 and minimize its relevance by saying somehow that all it is  
17 is a disclaimer or characterize it as a disclaimer to an  
18 advertisement. It's not a disclaimer to an advertisement.

19 The concept of advertising disclaimers have been  
20 used for a long, long time in a trademark context. We know  
21 that. But in the false advertising context where a product  
22 is described from a functionality perspective, we would  
23 submit the Court shouldn't be instructing the jury that an  
24 IFU somehow in some way is a disclaimer associated in any  
25 way with advertising.

1 MR. REILLY: Your Honor, all deference to Mr.  
2 Ryan, he is conflating FDA requirements into this case and  
3 what is at stake is the advertising. And they have been  
4 utilizing throughout this trial that disclosure in order to  
5 establish somehow that the meaning of AirSeal and what that  
6 does and air entrainment, what it means to try to change  
7 that meaning.

8 And the jury needs to know that when doctors  
9 don't read it, it's given a very cursory glance, that it  
10 doesn't carry the weight they are trying to afford to it.

11 THE COURT: We haven't found much case law on  
12 the point. But I am sort of informed by the discussion we  
13 had at sidebar over the slides you wanted to use, the FDA  
14 stuff. Does this play into that at all, that discussion we  
15 had at sidebar and the subsequent evidence?

16 MR. WILLE: Somewhat, Your Honor. I think our  
17 main point is this: There is really no evidence in this  
18 case that anyone has read these instructions for use. They  
19 have said, we give them to hospitals and the hospital reads  
20 it. Their own experts haven't read them. They are trying  
21 to create the impression to the jury that somehow the false  
22 advertising is fixed because these instructions for use are  
23 out there. This case law says, if there is a disclaimer in  
24 the advertising that it can be discounted. This disclaimer  
25 isn't in the advertising. It's not even close to the

1 advertising. So the message that is being delivered by the  
2 advertising is completely disconnected from the instructions  
3 for use.

4 The jury needs some understanding of the  
5 significance of things that are not with the advertising or  
6 in fine print somewhere else.

7 THE COURT: I agree with you. So what you are  
8 recommending, Mr. Wille, is that this language come out  
9 altogether?

10 MR. REILLY: I want --

11 THE COURT: That this language be included in  
12 its entirety.

13 MR. REILLY: I don't think disclaimer  
14 necessarily has to be in there, I think that is sort of a  
15 term of art in advertising. I think if we talk about the  
16 disclosure being removed, my preference is to keep it in,  
17 but that's an opportunity for the Court to find some middle  
18 ground --

19 THE COURT: I am looking for the middle ground.  
20 Accepting the middle ground proposal, how should it read?

21 MR. REILLY: If an advertisement or product  
22 literature contains a disclosure that purports to change the  
23 apparent meaning of a claim or render it literally truthful,  
24 but that is so inconspicuously located or in such fine print  
25 that readers tend to overlook it, it will not remedy the

1 false or misleading nature of the claim.

2 THE COURT: I completely agree with that.

3 MR. RYAN: Your Honor, we object to this.

4 THE COURT: That's what I just said. I may not  
5 have the robe on, but I am still the same guy. Let's  
6 respect the office.

7 MR. RYAN: I do. Greatly.

8 THE COURT: I understand your point. You made  
9 your objection. It's duly noted. We will move on.

10 MR. REILLY: That brings us to Page 22, Your  
11 Honor.

12 THE COURT: Whether challenged advertising...

13 MR. REILLY: Yes, Your Honor. There is a real  
14 issue here.

15 We started out with iterations here, not to  
16 bring them into the weeds, but consumer surveys have been an  
17 issue. There was initially an instruction trying to say --

18 THE COURT: Reflecting back on just our earlier  
19 discussion, it fits the facts of the case that have come in.  
20 I really do understand your point, Mr. Ryan. I understand  
21 your frustration with my ruling. That couldn't be clearer  
22 to me, that that is a correct ruling on that.

23 Maybe the Third Circuit will say I am wrong. We  
24 will see.

25 MR. REILLY: Going back to this instruction,

1 they are putting in this --

2 MR. RYAN: Where are we?

3 MR. REILLY: Page 22. Public reaction is the  
4 measure of commercial impact.

5 There is this language about a survey and the  
6 persuasiveness of a survey in order to establish what the  
7 purchasing public is understanding. But there is no survey  
8 consumer evidence in this case. We do have a survey but the  
9 survey goes to materiality. This is going to confuse the  
10 jury as to, okay, where is the survey, what am I looking  
11 for, why is that in there.

12 MR. RYAN: We agree, Your Honor. We actually  
13 had discussed --

14 THE COURT: I am glad you agree.

15 MR. RYAN: We had discussed changing this. The  
16 agreement was that --

17 THE COURT: You agree this should come out.

18 MR. REILLY: Yes.

19 MR. RYAN: We agreed that the language would be  
20 changed to remove usually turns on and insert instead may be  
21 proved by, may be proved by a consumer survey, and then  
22 continue to list additional ways that this could be proved,  
23 measure of an advertised impact.

24 That was a discussion Mr. Reilly and I had had.  
25 Not that the reference completely evaporates to a survey but

1 that it may be proved by a consumer survey or by, then we  
2 list the other evidentiary methodologies by which such  
3 deception could be proved.

4 MR. REILLY: Where I had an issue and we were  
5 trying to get some agreement before we came into court  
6 again, Your Honor, was on that language. I was trying to  
7 come up with something that would be reasonable. The  
8 difficulty here is when you are talking about Element 2,  
9 deception or a tendency to deceive, it really truly is just  
10 a tendency to deceive. That is why the presumptions are  
11 there on the literal falsity side of the claim.

12 I think we may have addressed them up front.  
13 Maybe we are safe here. But to inflate, to suggest somehow  
14 you need that consumer survey is dangerous.

15 If we have consumer survey in there, it should  
16 be sort of at the tail-end or being viewed as sort of  
17 another way to do it, anecdotal evidence. Here we have  
18 direct evidence. If we are going to talk about this in any  
19 degree or level, we should be talking about it as direct  
20 evidence of a diversion of sales or direct loss or loss by  
21 the plaintiff or circumstantial evidence that might be  
22 provided.

23 We have a lot of circumstantial evidence.  
24 Besides survey evidence, we have publications that we have  
25 put into evidence that are very important in establishing

1 confusion.

2 THE COURT: I agree. Do you want to try a shot  
3 at some language here?

4 MR. RYAN: One other point. We agree that there  
5 is other evidence. The standard which is important, which  
6 we need to make sure we cover, Your Honor, if we use the  
7 survey, it should be may. It certainly shouldn't be using  
8 terms of persuasiveness. I think we agree. But the  
9 language needs to be a substantial portion of the intended  
10 audience. That is the legal standard.

11 THE COURT: Is there disagreement about that?

12 MR. RYAN: I don't see the language in here. It  
13 should be. It's up top but not repeated down here.

14 MR. REILLY: If it is up top, Your Honor, it  
15 would be redundant for the jury to create additional  
16 language.

17 MR. RYAN: If you look, For you to find that a  
18 statement is true but misleading, and it goes on, we need to  
19 say the same thing as to what the proof is required.

20 It isn't just enough to prove -- you have to  
21 prove that there was deception or a tendency to deceive an  
22 essential segment of the intended audience.

23 I think you leave the jury kind of uncovered, if  
24 I may, by not repeating that language as to what the  
25 evidence, what it must show.

:21:12 1 THE COURT: I don't have any difficulty with  
:21:15 2 repeating that phrase, substantial segment of the audience,  
:21:19 3 Mr. Reilly. Do you want to see where that might be  
:21:30 4 inserted?

:21:30 5 MR. REILLY: We would say whether a challenged  
:21:34 6 advertising claim is deceptive may be proved on  
:21:39 7 persuasiveness of a consumer survey. We are taking out  
:21:43 8 persuasiveness.

:21:44 9 MR. RYAN: I would remove it.

:21:46 10 THE COURT: You had made another proposal. I  
:21:49 11 know we were going to reposition consumer survey.

:21:53 12 MR. RYAN: He was suggesting reordering it, not  
:21:56 13 put consumer survey first.

:21:58 14 MR. REILLY: If we say persuasiveness of --

:22:02 15 MR. RYAN: Why don't we say may be proved by,  
:22:05 16 rather than get rid of persuasiveness.

:22:08 17 MR. REILLY: May be shown. So direct evidence  
:22:16 18 or evidence of a diversion of sales or direct testimony or  
:22:25 19 by circumstantial evidence such as a survey.

:22:28 20 THE COURT: Direct testimony? Why direct  
:22:31 21 testimony?

:22:31 22 MR. REILLY: I am sorry, Your Honor. I took  
:22:33 23 that language from a case, Tenth Circuit case. Evidence of  
:22:38 24 a diversion of sale or customer confusion? I am trying to  
:22:44 25 figure out how to capture --



:22:46 1 THE COURT: What do you want to suggest, Mr.

:22:48 2 Ryan?

:22:48 3 MR. RYAN: What's the evidence --

:22:51 4 THE COURT: Why don't you read into the record  
:22:54 5 what you would like to propose. Write it down and see what  
:22:59 6 you can craft right there.

:23:00 7 MR. RYAN: Thank you.

:23:17 8 THE COURT: I agree that consumer needs to come  
:23:21 9 out altogether.

:23:26 10 It has no business in this part of the charge.

:22:46 11 MR. RYAN: Then, your Honor, if that's what  
:22:48 12 we're going to do, why don't we just say evidence? What may  
:22:51 13 be proved by evidence.

:22:53 14 MR. REILLY: But the problem with that, Your  
:22:55 15 Honor, it kind of leaves the jury hanging a little bit.  
:22:57 16 There are certain requirements and that is diversion of  
:23:00 17 sales.

:23:00 18 THE COURT: Yes.

:23:01 19 MR. REILLY: Customer conversion, salesperson  
:23:03 20 confusion, publications.

:23:04 21 THE COURT: Yes. I agree. I agree. Let's give  
:23:08 22 them some guidance. Yes.

:23:12 23 MR. RYAN: And then we would include that a  
:23:24 24 substantial portion of the intended audience was deceived.  
:23:27 25 Is that how we would end it?

:23:30 1 MR. REILLY: I don't believe that's appropriate,  
:23:31 2 Your Honor.

:23:31 3 MR. RYAN: That's the language, Your Honor. You  
:23:33 4 said you thought we would pull down from the top.

:23:35 5 THE COURT: No. I said that I didn't have a  
:23:39 6 problem, Mr. Reilly, with repeating.

:23:41 7 MR. REILLY: Understood, Your Honor. But I  
:23:43 8 think in the context of how we're modifying this language  
:23:46 9 and you've already gotten substantial segment of the  
:23:48 10 audience up front, that's acting as an umbrella over the  
:23:52 11 confusion language.

:23:53 12 THE COURT: Read the language without that  
:23:54 13 substantially.

:23:55 14 MR. REILLY: So whether a challenged advertising  
:23:58 15 statement is deceptive may be proved by evidence of  
:24:01 16 diversion of sales, customer confusion, salesperson  
:24:05 17 confusion, publications.

:24:11 18 I would suggest something broad, but something  
:24:14 19 like, or other anecdotal evidence, but if you feel that that  
:24:18 20 is too vague --

:24:18 21 THE COURT: Or other evidence.

:24:20 22 MR. REILLY: Or other evidence would be fine.

:24:22 23 THE COURT: Or other evidence, period.

:24:23 24 MR. RYAN: Your Honor, that's actually helpful.

:24:25 25 THE COURT: All right.

:24:25 1 MR. RYAN: Then what we should do, I think, is,  
:24:28 2 whether a challenged advertising statement deceives a  
:24:32 3 substantial segment of the audience may be proved by, I  
:24:37 4 think that would be appropriate then.

:24:38 5 MR. REILLY: No.

:24:39 6 MR. RYAN: There should be no objection to that.

:24:40 7 MR. REILLY: I disagree, Your Honor. We're  
:24:42 8 talking about fact of damage right here, and fact of damage,  
:24:45 9 as the cases have demonstrated, is that even a few instances  
:24:48 10 of confusion, it would be very compelling.

:24:50 11 MR. RYAN: That's absolutely not the legal  
:24:52 12 standard.

:24:53 13 THE COURT: So I understand, Mr. Ryan, you have  
:24:55 14 your exception, and I'm going to accept the language that  
:24:58 15 you've read into the record as -- I think I offered an edit  
:25:05 16 or two.

:25:06 17 MR. REILLY: Yes. I think at the end we had any  
:25:08 18 evidence instead of anecdotal.

:25:10 19 THE COURT: Yes. The next is on the next page?

:25:13 20 MR. RYAN: Your Honor, may I just be heard on  
:25:16 21 this?

:25:16 22 THE COURT: No. I'm not going to be here all  
:25:18 23 night.

:25:19 24 MR. RYAN: I understand, Your Honor, but --

:25:20 25 THE COURT: Nor are my reporters, nor is my

1 staff.

2 MR. RYAN: Your Honor --

3 THE COURT: The way that this has been  
4 presented, you don't want to get me started. You really  
5 don't, so you should stop. You should stop.

6 MR. RYAN: Okay.

7 THE COURT: Let's go on to the next one.

8 MR. REILLY: Your Honor, on Page 23.

9 THE COURT: Yes.

10 MR. REILLY: This came up when you asked for the  
11 limiting instruction, is where we're sort of having some  
12 disparity.

13 You may recall there was an issue about  
14 salesperson confusion and Ms. Moriarty was on the stand.  
15 You said you can only consider it for certain purposes.

16 THE COURT: Right.

17 MR. REILLY: It seems to me the sentence above  
18 that bracketed language is sufficient to provide that  
19 limiting instruction that you asked for. The bottom part of  
20 the language creates almost a double burden in order to  
21 establish what can be utilized or referred to.

22 THE COURT: So, Mr. Reilly, you're talking --  
23 so you are talking about eliminating or including this  
24 one?

25 MR. WILLE: Can I be heard, Your Honor?

:26:20 1 THE COURT: Yes.

:26:21 2 MR. WILLE: This last sentence talks about where  
:26:23 3 a witness says, oh, I'm confused. I thought the AirSeal is  
:26:28 4 X. There has not been any testimony of that, to that type  
:26:31 5 of confusion in this case.

:26:33 6 THE COURT: Right.

:26:33 7 MR. WILLE: All of the confusion evidence that  
:26:35 8 was presented were people saying to Ms. Moriarty or one of  
:26:39 9 these other witnesses, I think that -- why do I need your  
:26:43 10 product? This heats and humidifies, or my understanding is  
:26:48 11 the AirSeal didn't entrain air. There's nobody who  
:26:51 12 expressed that said, I'm confused, which is I think what  
:26:56 13 your Honor's ruling was saying, that evidence can't come in,  
:26:58 14 and I don't think any of that evidence was presented. So I  
:27:01 15 don't think we need this instruction.

:27:02 16 MR. RYAN: We agree, Your Honor.

:27:03 17 THE COURT: Okay.

:27:04 18 MR. RYAN: The only thing we would say about  
:27:05 19 this section is, we shouldn't be calling out the testimony  
:27:07 20 of one particular sales rep. I think what we should be  
:27:11 21 doing is, you heard the live testimony of sales  
:27:15 22 representatives regarding conversations with customers. I  
:27:17 23 think that's how the instruction should read rather than one  
:27:20 24 specific sales rep being called out.

:27:22 25 MR. REILLY: That would be acceptable, Your

1 Honor.

2 THE COURT: Okay.

3 MR. RYAN: Thank you.

4 Then the last portion, Your Honor, is the  
5 evidence of actual confusion.

6 THE COURT: Yes?

7 MR. RYAN: That sentence and the one below it,  
8 the rarity of such evidence, even a few incidents probative  
9 of the likely confusion. Again, we think that's  
10 inappropriate in this instruction.

11 THE COURT: Did you want to say something about  
12 it?

13 MR. REILLY: Your Honor, I think where you  
14 pointed out before, where you are trying to instruct the  
15 jury on what they've heard, we've presented much of our  
16 testimony through salesperson confusion as well as some  
17 publications, et cetera. Evidence of confusion like this is  
18 very difficult to come by.

19 THE COURT: But where is that instruction coming  
20 from? And not the authority, but those words, evidence of  
21 actual confusion is difficult to find. Where is -- go  
22 ahead.

23 MR. REILLY: I'm sorry. I thought it came from  
24 the case that I was citing, Your Honor.

25 THE COURT: Which -- the Coz case?

:28:22 1 MR. REILLY: I believe so. I'm sorry, Your  
:28:24 2 Honor. It says -- the quoted language was, very little  
:28:27 3 proof of actual confusion would be necessary to prove  
:28:30 4 likelihood of confusion. That's not the right case, Your  
:28:32 5 Honor. I'm sorry. I apologize.

:28:33 6 THE COURT: Yes.

:28:34 7 MR. RYAN: It should be removed for the  
:28:36 8 additional reason. This is a concept, especially here,  
:28:38 9 regarding very, very specific to trademark, the rarity of  
:28:43 10 evidence and likely confusion. It does not work.

:28:45 11 THE COURT: I don't know where that language is  
:28:47 12 coming from in this case, in this case.

:28:50 13 MR. RYAN: We don't think it applies.

:28:51 14 THE COURT: All right.

:28:52 15 MR. RYAN: And what you did, Mr. Reilly I think  
:28:54 16 artfully asked for in the paragraph before, is just to list  
:28:56 17 out the type of evidence that the jury can consider for the  
:29:01 18 purposes of establishing the section.

:29:03 19 THE COURT: Why does the Court get to say that  
:29:04 20 this evidence is rare?

:29:06 21 MR. RYAN: It shouldn't, Your Honor.

:29:07 22 THE COURT: That's my question.

:29:09 23 MR. REILLY: Well, we're taking that language  
:29:11 24 right from that Coz case, Your Honor.

:29:13 25 THE COURT: And that's a trademark case?

:29:15 1 MR. RYAN: Yes.

:29:15 2 THE COURT: I don't know that, you know --  
:29:18 3 right?

:29:18 4 MR. REILLY: Well, Ferring makes pretty clear,  
:29:21 5 Your Honor, that it's very appropriate for courts to --

:29:23 6 THE COURT: But let's, for a moment, discuss the  
:29:26 7 law on both areas.

:29:28 8 MR. REILLY: Sure.

:29:28 9 THE COURT: Where does the Court get that  
:29:30 10 language from in the Coz case?

:29:32 11 MR. REILLY: I'm trying to find the case, Your  
:29:34 12 Honor.

:29:34 13 THE COURT: Okay. That's a Third Circuit  
:29:35 14 opinion?

:29:36 15 MR. REILLY: I believe so, Your Honor.

:29:48 16 MR. WILLE: Mr. Ryan, do you have the case?

:29:51 17 MR. RYAN: Pardon?

:29:52 18 MR. WILLE: Do you have the case?

:29:53 19 MR. RYAN: I'm looking for it. I don't think I  
:29:55 20 do. I don't.

:30:02 21 MR. REILLY: You do?

:30:03 22 MR. RYAN: I don't. I'm sorry. I do not.

:30:05 23 THE COURT: And even accepting, Mr. Reilly, as I  
:30:08 24 do your proposition that we can discuss -- discussions bleed  
:30:22 25 over, trademark to false, false --



:30:26 1 MR. REILLY: Sure.

:30:27 2 MR. RYAN: Not in this context, Your Honor.

:30:28 3 THE COURT: And that's the point, I think, that  
:30:30 4 I'm in agreement with.

:30:31 5 MR. REILLY: But, Your Honor it is confusion  
:30:33 6 evidence that we're talking about, and we're telling the  
:30:39 7 jury up front they need to look at substantial...

:31:02 8 (Pause. )

:31:11 9 THE COURT: Mr. Reilly, there is this language  
:31:13 10 in the case. The Court wrote, "Because," quote, "reliable  
:31:21 11 evidence of actual confusion is difficult to obtain in  
:31:24 12 trademark and unfair competition cases."

:31:27 13 MR. REILLY: Yes, sir.

:31:28 14 THE COURT: You don't think this language should  
:31:31 15 be confined to that as calling out trademark and unfair  
:31:38 16 competition?

:31:39 17 MR. REILLY: And unfair competition is the  
:31:41 18 umbrella name for call sabotage, and it covers the Lanham  
:31:46 19 Act, Your Honor.

:31:47 20 THE COURT: That is true. That is true. In the  
:31:51 21 excerpt my law clerk drew out for me on this, we don't know,  
:31:55 22 frankly, where the Court derives this language, the panel  
:31:58 23 that wrote this opinion. I'm not comfortable with it.

:32:03 24 Did you find it?

:32:04 25 MR. REILLY: I'm looking at it now, Your Honor.

1 If I could just have a moment?

2 THE COURT: The Court writes, We have recognized  
3 however that evidence of actual confusion, quote, is  
4 difficult to find, ellipsis, because many instances are  
5 unreported.

6 I am not comfortable with this language.

7 MR. REILLY: It is very similar, actually, Your  
8 Honor, to what Judge Robinson found in the other case that  
9 we were looking at. She pointed out that, you know, this  
10 evidence is very difficult to find. It's not something that  
11 comes up. It's rare. We have a lot of that evidence here.  
12 I think it's very helpful to the jury. It is helpful also  
13 for them to understand how to balance that in the context of  
14 a false advertising case.

15 Absent that instruction, it's hard for them to  
16 really grasp exactly the proportion and importance of that  
17 kind of evidence to be considered while they deliberate  
18 these facts.

19 THE COURT: I think there is a lot of evidence  
20 in the case that stands, could be found by the jury to stand  
21 for a number of different propositions. I am uncomfortable  
22 with raising this evidence with language like this. The  
23 rarity of such evidence makes even a few instances probative  
24 of the likelihood of confusion. I am not comfortable in  
25 this case, in the context of this case, our facts, giving

1 this jury that instruction.

2 MR. REILLY: What if we were to give some  
3 perhaps -- I am not sure what the language is exactly that  
4 is troubling Your Honor.

5 THE COURT: I just read it to you.

6 MR. REILLY: I read it as well. I was looking  
7 to see if there was some type of balance that we could  
8 strike.

9 MR. RYAN: Your Honor, we covered this in the  
10 prior language. The Court ran through the types of language  
11 that the jury can consider. You talked about articles and  
12 other things. That was what the list -- I thought Mr.  
13 Reilly recommended to the Court removing the survey  
14 component that would cover this.

15 MR. REILLY: Your Honor, what if we moved it to  
16 something like evidence of actual confusion is difficult to  
17 find and even a few instances can be probative.

18 THE COURT: Let me just back up a little bit off  
19 what I said a moment ago. An analogy came to mind or a  
20 similar circumstance, in terms of intent, understanding  
21 intent and how difficult it can be to divine an individual's  
22 intent or state of mind, and ultimately, and oftentimes, you  
23 have little evidence, it usually comes up in the criminal  
24 context of a perpetrator's, an actor's state of mind. But  
25 you can't look to other evidence.

:36:49 1 Say that again.

:36:50 2 MR. REILLY: Evidence of actual confusion is  
:36:53 3 difficult to find, but -- and even a few instances  
:36:58 4 probative of confusion -- may be probative, I mean.

:37:09 5 Evidence of actual confusion is difficult to  
:37:12 6 find and even a few instances may be probative of confusion.

:37:25 7 MR. RYAN: Your Honor, we disagree. If I may,  
:37:28 8 just so the Court has the benefit. The *Facienda v. NFL*  
:37:35 9 *Films* decision, in that the Court, the Third Circuit, 2008  
:37:40 10 decision, what the Court was saying there is different. In  
:37:46 11 an action brought under another part, this is 43(a) of the  
:37:50 12 Lanham Act for false advertising, if its claim is not that  
:37:55 13 the advertising was false but that it was misleading, it  
:37:58 14 must prove the public was actually misled or confused by it.

:38:02 15 This is a real serious issue of conflating the  
:38:04 16 standards between a trademark case and a false advertising  
:38:07 17 case.

:38:08 18 Their burden is not to say, with a misleading  
:38:12 19 statement, that there is a potential for confusion and it's  
:38:15 20 rare to find, which is a trademark concept. When it comes  
:38:18 21 to a false advertising case, they must prove that the public  
:38:21 22 was actually misled or confused by the statement, a  
:38:26 23 substantial portion of the public.

:38:27 24 What they are doing is eviscerating, we think,  
:38:30 25 what is required by them to show that the consuming public

1 was somehow deceived or misled by some false advertising.

2 THE COURT: Why does that eviscerate and why is  
3 that conflation? I don't understand exactly.

4 MR. RYAN: They are pulling in the trademark  
5 concept of likelihood of confusion.

6 The question in a false advertising case is not  
7 likelihood of confusion. Their burden is that they must  
8 show --

9 THE COURT: Actual confusion.

10 MR. RYAN: No. They must show deception.

11 THE COURT: Actual deception.

12 MR. RYAN: Yes. They have to show that a  
13 consumer was deceived, a substantial portion of that  
14 relevant market was deceived.

15 This is significantly lowering their standard,  
16 we think, Your Honor.

17 THE COURT: Why does that lower the standard?

18 MR. RYAN: You are saying only a few instances  
19 could be sufficient. That is not what the standard is.

20 THE COURT: I don't think that is what it says.

21 MR. RYAN: I think it is what it says, what they  
22 are doing, even a few instances probative of confusion --  
23 that is not the standard in false advertising. They have to  
24 prove that a substantial portion of the receiving public of  
25 that ad was deceived.

1           That is much different than what Mr. Reilly is  
2           telling the Court applies, especially the importation here  
3           of this concept of likelihood of confusion is not right for  
4           a false advertising claim.

5           MR. REILLY: Your Honor, Faring speaks to the  
6           two statutes. The case that Mr. Ryan was referring to was a  
7           false endorsement case that dealt with unfair competition  
8           and utilizing someone's voice and the impact that might have  
9           on being a false association or false endorsement of that  
10          celebrity. It is a different animal. It is not the same.  
11          It can't be equated here.

12          Faring specifically spells out, Third Circuit,  
13          Footnote 6, Trademark infringement and false advertising  
14          claims both arise under 43(a)(1) of the Lanham Act and  
15          courts often rely on trademark infringement precedent in  
16          deciding false advertising cases, as both types of cases  
17          address irreparable injuries in the form of reputational  
18          harm and loss of goodwill.

19          That is exactly what we are talking about here,  
20          we are talking about, harm, confusion, harm to our goodwill.

21          MR. RYAN: We are not talking about that here.

22          They have a burden --

23          THE COURT: I know what their burden is. I am  
24          going to accept --

25          MR. REILLY: Evidence of actual confusion is

1 difficult to find, and even a few instances of actual  
2 confusion may be probative.

3 MR. RYAN: Probative of what, Your Honor? Of  
4 deception?

5 THE COURT: What does the first part say.

6 MR. REILLY: Evidence of actual confusion is  
7 difficult to find.

8 THE COURT: Evidence of actual confusion --

9 MR. RYAN: Of what?

10 THE COURT: Of actual confusion.

11 MR. RYAN: It has to be probative to show that a  
12 substantial portion of the consuming public was deceived.  
13 It can't just be probative.

14 THE COURT: Let's move on to the next one.

15 MR. REILLY: Your Honor, this relates to the  
16 salesperson confusion. I believe this is SurgiQuest's  
17 objection. We went over this in detail during the trial.  
18 This instruction is really just to give them an  
19 understanding of what that salesperson confusion is about  
20 and why it is relevant.

21 THE COURT: This is the bracketed language at  
22 Page 24?

23 MR. REILLY: Yes, Your Honor. As well as the  
24 issue of the publications that Mr. Wille raised with the  
25 Cuisinart case is the last sentence of that paragraph.

:42:07 1 THE COURT: What is your difficulty with this  
:42:08 2 language?

:42:09 3 MR. RYAN: This is already covered in the prior  
:42:12 4 paragraph that the Court laid out with respect to the type  
:42:14 5 of evidence that can be considered. Now we are calling this  
:42:17 6 out as a special category unto itself.

:42:20 7 THE COURT: Are we removing Ms. Moriarty's  
:42:23 8 callout?

:42:24 9 MR. RYAN: Yes, Your Honor. It was agreed.

:42:29 10 THE COURT: In the prior paragraph. She is  
:42:31 11 called out twice.

:42:33 12 MR. RYAN: Yes.

:42:37 13 THE COURT: Mr. Reilly, Mr. Ryan objects that  
:42:39 14 this is covered, this concept in this bracketed language is  
:42:43 15 already covered in this brief paragraph.

:42:46 16 MR. REILLY: I am not certain, Your Honor, he  
:42:48 17 has been raising this point about substantial confusion. We  
:42:52 18 have salesperson confusion. If they are confused, they are  
:42:55 19 spreading that to a larger population that might be -- that  
:42:58 20 would be sort of reflective of their activities and how they  
:43:02 21 handle it. That may not be apparent. I think that's a very  
:43:05 22 important fact for them to understand.

:43:09 23 MR. RYAN: If it wasn't, that should be added  
:43:11 24 into the type of evidence --

:43:12 25 THE COURT: This concept needs to be included.



1 I am not invested in the language. But I agree with you  
2 that the concept needs to be in there. To the extent that  
3 you can meld this into -- part of, as I understand, Mr.  
4 Ryan, your objection, is this is repetitive.

5 MR. RYAN: It is repetitive. It calls out a  
6 special category of evidence. If we include it into the  
7 section that you had discussed with us previously, I have no  
8 objection.

9 MR. REILLY: I do understand that, Your Honor.  
10 Maybe we might be able to meld some of this language, and I  
11 will try to do that now and maybe take one of these  
12 sentences and try to perhaps rework it and move it up, if  
13 that would be convenient. I am not sure how far we need to  
14 move it up, because we are just talking about the sentence  
15 above it where we just changed that to talk about confusion.

16 I am mistaken, I apologize. I was looking at  
17 the wrong page. I will work with that language and see if I  
18 can come up with something.

19 MR. RYAN: If I may, your Honor, just one other  
20 concept on that point.

21 THE COURT: Yes.

22 MR. RYAN: What I think the jury should be  
23 instructed is the concept that consumers were deceived by  
24 the advertising, not confused, and I think when it comes to  
25 the evidence that's being listed, that should be what we're

1 instructing the jury.

2 THE COURT: Deceived?

3 MR. RYAN: Yes. I think that's a significant  
4 substantial portion of the consumers would be deceived, not  
5 that they are confused.

6 THE COURT: Okay.

7 MR. RYAN: I think that deflates the issue.

8 THE COURT: I agree. Did you hear that?

9 MR. REILLY: I'm sorry.

10 THE COURT: Mr. Ryan has proposed changing the  
11 word "confused" to "deceived," and I agree with that.

12 MR. REILLY: Which word is he talking about,  
13 Your Honor?

14 MR. RYAN: When we do the list of the potential  
15 types of evidence that could be used if a salesperson is  
16 included, it should be to deceive the substantial portion of  
17 that market, not confuse. The standard is deception,  
18 whether or not an advertisement deceives the consuming  
19 public.

20 I think we're importing too much of the  
21 confusion language as opposed to the advertising, deception  
22 language. I think you and I can work it out.

23 MR. REILLY: I don't know if I'm wed to that  
24 yet, Your Honor.

25 THE COURT: I am.

:44:41 1 MR. REILLY: Understood.

:44:43 2 THE COURT: Next?

:44:47 3 MR. REILLY: Your Honor, just to understand,  
:44:49 4 we're keeping in this paragraph, but we're putting in  
:44:55 5 deceived instead of confused.

:44:57 6 THE COURT: You were working on some language?

:44:59 7 MR. REILLY: Yes.

:44:59 8 MR. RYAN: We were going to take salesperson  
:45:01 9 confusion and move that into the list of other evidence that  
:45:04 10 we discussed.

:45:05 11 THE COURT: He's trying to do that now.

:45:07 12 MR. REILLY: Yes.

:45:08 13 MR. RYAN: We're not keeping the paragraph.

:45:09 14 THE COURT: Exactly, Mr. Ryan, but we're going  
:45:16 15 to give Mr. Reilly a few minutes to do that.

:45:18 16 MR. RYAN: Thank you, Your Honor.

:45:19 17 THE COURT: And I will be right back.

:45:41 18 (Pause.)

:49:52 19 THE COURT: How you are you making out,  
:49:54 20 Mr. Reilly?

:49:54 21 MR. REILLY: Yes, you. What I had thought I had  
:49:59 22 proposed was to have some qualifying language after that,  
:50:01 23 where we said, we went through the litany of the version of  
:50:03 24 sales, customer confusion, salesperson confusion,  
:50:04 25 publications, articles or other evidence of confusion, and

1 then I was thinking or proposing a brief explanation of the  
2 salesperson confusion as being able to establish a tendency  
3 to deceive as that is evidence that consumers that the  
4 salespersons that act with will also be deceived.

5 THE COURT: Did you have specific language you  
6 wanted to propose to Mr. Ryan on that point?

7 MR. REILLY: That was the language.

8 THE COURT: That's the language?

9 MR. RYAN: If we simply add in the salesperson  
10 confusion concept into the list of evidence, the jury can  
11 conclude, then I think, while we don't -- we object to it, I  
12 think that's something at least for now we can agree to for  
13 the purposes of finalizing this instruction.

14 THE COURT: All right.

15 MR. RYAN: We don't want to have a separate  
16 callout, another callout for salesperson confusion. He  
17 has listed it as a type of evidence that the jury may  
18 consider.

19 THE COURT: Okay.

20 MR. RYAN: Among other things for the purposes  
21 of establishing whether or not an advertisement --

22 THE COURT: So what is the amendment you want to  
23 add to his language?

24 MR. RYAN: I think he added the salesperson  
25 confusion into -- he has already done it. It's into his

1 list.

2 MR. REILLY: No. It was on that list. The  
3 problem here, Your Honor, is that the salesperson confusion  
4 is a little bit of a different animal. I mean, you had a  
5 sidebar on it, it was discussed in court. It's not a  
6 concept that's readily understandable I think by the jury as  
7 to what that kind of evidence means.

8 THE COURT: Why?

9 MR. REILLY: Because it may not be readily  
10 apparent to them that that could be, that could be  
11 demonstrative of confusion level at the customer level or at  
12 the consumer level. I don't know if that's --

13 THE COURT: You suggest, and I think this has  
14 been the subject of discussion, that salesperson confusion  
15 can be evidence of consumer.

16 MR. REILLY: Yes, sir.

17 THE COURT: Confusion.

18 MR. REILLY: Yes, Your Honor.

19 THE COURT: And a jury needs to understand that  
20 concept. There's evidence in the case that would support  
21 making a finding along those lines. So what is the  
22 difficulty?

23 MR. RYAN: Well --

24 THE COURT: I don't understand. So that's in  
25 the case. Now, what is the problem we have?

:52:07 1 MR. REILLY: My concern though is whether or not  
:52:09 2 when they go back to deliberate, that they'll understand  
:52:11 3 what the import of that type of confusion evidence -- it's  
:52:15 4 a little bit different than your classic customer confusion.

:52:18 5 THE COURT: No. Let's not over-lawyer this,  
:52:21 6 Mr. Reilly.

:52:22 7 MR. REILLY: Understood, Your Honor.

:52:24 8 THE COURT: Here's a lay jury, so come up with  
:52:27 9 some language that you two can agree upon.

:52:42 10 MR. REILLY: How about if we do something of a  
:52:44 11 parenthetical in that list, where we have the salesperson  
:52:46 12 along with publications and the other evidence of confusion,  
:52:49 13 if we put in a parenthetical after salesperson confusion,  
:52:54 14 saying something like, which may be evidence of consumer  
:52:57 15 confusion.

:53:01 16 MR. MOORE: Or even put a comma, which may be  
:53:03 17 evidence.

:53:03 18 THE COURT: Comma, evidence of confusion.

:53:05 19 MR. REILLY: Right.

:53:06 20 THE COURT: Of consumer confusion. Yes.

:53:08 21 Let me give you some further instructions for  
:53:10 22 the rest of the evening. I've got 13, I counted 13  
:53:13 23 discrete objections that remain. What progress did you  
:53:16 24 folks make?

:53:18 25 MR. REILLY: Your Honor, I believe that we had

two different theories or understandings of where the law ended and began with regard to liability and damages.

THE COURT: My staff and I and my court reporters, we're not going to stay here until 8:00 o'clock tonight while you beat our brains in with this kind of discussion. I'm not doing it.

So what do you want to do? I'm going to instruct -- and if you leave me to my own devices, I will cut and paste these on my own.

MR. REILLY: Understood, Your Honor.

THE COURT: So you're going to have to -- quite frankly, you're not being reasonable with one another, and you are making arguments that are really dancing on the head of a pin and I'm getting frustrated and about to lose my patience.

MR. RYAN: Right.

THE COURT: Okay. So what are we going to do? I've got 13 tabs here. I don't think -- yes, you've succeeded in reducing it from 152 pages to 52, or 149, whatever it was to 50, but that was patently ridiculous in the first place.

MR. REILLY: Your Honor, one thought or one issue where we ran into a real problem from the very get-go is, we were trying to come up with instructions for liability and an instruction for damages. The other side

1 wanted to break them into each of the elements, thought that  
2 became more confusing, more difficult, but we tried to make  
3 that concession and broke out the elements on the false  
4 advertising claim.

5 I think a lot of our issue in terms of what is  
6 probably next, I think we've resolved a lot of the issues in  
7 terms of liability, really comes up on the damages side.

8 My thought or my recommendation is, we propose  
9 to you several or a few pages, whatever it is, to establish  
10 what the damage claims are. It should be no more than about  
11 two or three pages as opposed to a litany of discussion,  
12 which I would propose, if I could get back to a computer,  
13 put that together and submit it to the Court. If counsel  
14 wants to do the same in terms of their damage issue, then  
15 maybe that's another way to reach a bargain. I'm trying to  
16 be creative, Your Honor.

17 THE COURT: I think that's a reasonable  
18 approach.

19 Mr. Ryan?

20 MR. RYAN: I don't think we have on the damages  
21 side, Your Honor -- the only threshold difference between  
22 the parties is what Mr. Reilly has done is put all of the  
23 elements of damage together, meaning lost profits,  
24 corrective advertising, together. We think we shouldn't be  
25 doing that. What we think the jury should be instructed is



1 to a separate instruction as to each one of those from the  
2 damages perspective, because they are different.

3 What they require is different.

4 We don't think it's any longer. It just calls  
5 out each damages section, if you will, separately, which is  
6 what I think we should be doing to make sure the jury isn't  
7 confused as to what section of damages we are talking about.

8 I don't think there is that much to do.

9 THE COURT: What is your reaction to what he  
10 just said?

11 MR. REILLY: My reaction, Your Honor, is it  
12 really doesn't quite address the problem, because we have  
13 certain thoughts about the presumption and how they apply,  
14 how intent relates into this matter, and I think, you know,  
15 we could argue till the cows come home as you have seen. I  
16 think it makes better sense for us to try to put in some of  
17 the instructions on damages to you as we see them to be  
18 appropriate to reflect the law, and to be clear to the jury.  
19 We can pass them to the other side if you like. It hasn't  
20 gotten us anywhere. If they would like to submit what they  
21 believe is an appropriate set of instructions, I don't want  
22 to put the burden on your court, Your Honor. I am just  
23 trying to think creatively.

24 THE COURT: How long will it take you to do  
25 that?

:57:43 1 MR. REILLY: In a few hours, Your Honor,  
:57:45 2 tonight, maybe earlier.

:57:48 3 THE COURT: Okay. We are going to proceed in  
:57:50 4 that fashion. I will have you send it to my law clerk.

:57:57 5 MR. REILLY: Thank you, Your Honor.

:57:58 6 THE COURT: She and I will communicate during  
:58:00 7 the course of the evening. Of course, Mr. Ryan, do you want  
:58:07 8 to submit your own independently, do you want to feed off  
:58:11 9 what Mr. Reilly is going to do?

:58:13 10 MR. RYAN: I think it makes sense for us to try  
:58:16 11 to simplify the broken out elements of damage for the Court.

:58:19 12 THE COURT: Simple is good. Simplifying is  
:58:22 13 good.

:58:22 14 MR. RYAN: That is what we would like to do.

:58:24 15 MR. REILLY: We will we will submit it as well.

:58:28 16 THE COURT: If the two of you could talk before,  
:58:31 17 it would be very helpful if you could agree on one  
:58:34 18 submission. If there are some nits that remain, then my law  
:58:38 19 clerk and I will discuss them.

:58:41 20 But I am just saturated. We are not going to  
:58:45 21 sit here and do what we have been doing for the rest of the  
:58:47 22 evening. It is not going to happen.

:58:50 23 I want to put this to bed tonight, so you can  
:58:52 24 have your folks put the instructions in shape.

:58:55 25 I have given you the revised last two pages of

1 the deliberation and verdict.

2 MR. RYAN: Thank you, Your Honor.

3 THE COURT: The verdict form. Where are we?

4 MR. REILLY: We have a draft together. This  
5 obviously might impact where that draft leads.

6 MR. RYAN: May we ask a question on the verdict  
7 form?

8 THE COURT: Sure.

9 MR. RYAN: It is a more complicated issue,  
10 because the way that we understand the claim has to go in is  
11 all the elements have to be established and damages proved  
12 on a false advertising claim. The way the evidence has come  
13 in, there hasn't been any separation on a claim basis as to  
14 which claim they are alleging has been established or for  
15 the jury to even understand which claim they are  
16 considering.

17 We think that the only way to do it, given the  
18 fact they have all these claims, is we have to at least  
19 provide the jury the claim they are saying was false,  
20 whether it was -- whether it was misleading, whether it  
21 intended to deceive the jury, and whether that specific  
22 claim caused harm. We don't know another way to do it, Your  
23 Honor. We don't think it's appropriate for the jury to get  
24 all the claims at once and try to figure out what damage, if  
25 any, was caused by a particular claim.

1                   That is the reason for part of the complication  
2 with the jury verdict form.

3                   MR. REILLY: Your Honor, it seems to me that  
4 this is a case where you don't need to do that. You don't  
5 need to list out each and every language. These claims,  
6 they have been presented to the jury and this Court since  
7 pretty much the beginning, it has been to sort of identify  
8 them by categories. That would be a middle ground for us to  
9 sort of approach that, is to provide those categories as to  
10 the false claims that are at issue, I think there is three,  
11 maybe four, I think that might be a reasonable way for the  
12 jury to handle it.

13                   It would still address the claims in the case  
14 and get to the bottom and give them something to work with.

15                   THE COURT: I was looking for my copies of the  
16 initial proposed verdict forms. My recollection of them is  
17 they were both rather long.

18                   MR. RYAN: Your Honor, the length -- I will give  
19 you an example. What if the jury concludes that heat and  
20 humidity was misleading but not material by way of example.  
21 If the jury were to conclude that the heat and humidity  
22 comments were misleading but they weren't material, that  
23 pulls out any damage from a lost profits perspective that  
24 can be recovered by Lexion for its two products, because  
25 those two products have heat and humidity. It's an

1 essential element of those.

2 Or if it's determined by the jury that heat and  
3 humidity wasn't a material factor for the purchaser, there  
4 would be no damages. There couldn't be any damages.

5 THE COURT: Double-sided, the form you  
6 submitted, the so-called joint proposed verdict form was 54  
7 pages, double-sided.

8 MR. REILLY: Your Honor, I have drafted one that  
9 is a couple of pages that might be something we can work off  
10 of. I haven't gotten a chance to present it to the other  
11 side.

12 MR. RYAN: Your Honor, it is so long because at  
13 the time --

14 THE COURT: I am not going to do that to my  
15 jury.

16 MR. RYAN: We are in absolute agreement.

17 THE COURT: You don't need to waste your breath  
18 and inflict it on my hearing as to why it is so long.

19 It's ridiculous that it is this long, that it  
20 was submitted to a Court is ridiculous.

21 Mr. Buckson is making copies.

22 MR. REILLY: Your Honor, in the interim, while  
23 we are sitting here, what I had mentioned, the form that I  
24 have provided does not include the middle ground we were  
25 suggesting. But I think, the way the evidence has come in

1 here, as we have seen it, three or four groupings of claims  
2 on our side, I can't speak to the SurgiQuest side, that is  
3 how we presented the claims, I think we might be able to  
4 group them in that fashion in a way that would be workable  
5 for a jury to understand. I haven't proposed that language,  
6 but it is something that we could do.

7 THE COURT: You are proposing, again, to do  
8 what?

9 MR. REILLY: What we could do with it, Your  
10 Honor, right after the verdict form title or heading, we  
11 could identify the groups of claims on top, three or four,  
12 whatever they are, however we believe that should be worded,  
13 I haven't done that language yet, but then from there work  
14 down, have the jury have the predicate of the claims that  
15 they are looking at, this is those group claims, then they  
16 have the form to go through.

17 MR. RYAN: Your Honor, the jury needs to decide  
18 whether a specific claim -- let's assume you have a category  
19 of air and there are four allegations of false advertising  
20 under air. The jury is required under 1125 to go through  
21 and determine which if any of those claims were false, which  
22 deceived, which caused injury, which were material. What  
23 they want to do is put them into mini-categories and have  
24 the jury consider all of the claims under a particular  
25 category at once. We submit that that is improper.

:05:04 1 THE COURT: What would you propose?

:04:20 2 MR. RYAN: They have to decide which of the  
:04:22 3 claims -- maybe it's four, total, three, total. If they are  
:04:25 4 submitting to the jury for the jury to consider --

:04:28 5 THE COURT: Have you submitted a proposed  
:04:33 6 revised verdict form for my consideration? Here we are on  
:04:33 7 the eve of being instructed. You have not submitted  
:04:38 8 anything.

:04:38 9 MR. RYAN: Your Honor, we laid out for the  
:04:39 10 Court -- we haven't, because we laid out for the Court --

:04:42 11 THE COURT: You need to submit something.

:04:43 12 MR. RYAN: Fine. We will. Thank you, Your  
:04:45 13 Honor.

:04:45 14 THE COURT: You submit whatever you are going to  
:04:47 15 submit.

:04:48 16 MR. RYAN: Fair enough.

:04:48 17 THE COURT: Submit it at the same time --

:04:50 18 MR. RYAN: May I ask which question know.

:04:51 19 THE COURT: What is it?

:04:52 20 MR. RYAN: Which claims are we submitting on?  
:04:54 21 Which claims is he asking -- we need to know that, Your  
:04:56 22 Honor.

:04:56 23 THE COURT: You have claims as well.

:04:59 24 MR. RYAN: Your Honor, we need to know -- when I  
:05:01 25 say claims, I need to know, we need to know which statements

1 they are asking the jury to determine are false, misleading,  
2 material, and which ones they claim cause damage. I need to  
3 know which specific false advertising in these buckets they  
4 are submitting to the jury. Which ones? Maybe they want to  
5 pick two or three. We can narrow this whole thing down.

6 THE COURT: Why is the onus just upon  
7 Mr. Reilly?

8 MR. RYAN: It's his claim. It's his burden,  
9 Your Honor.

10 THE COURT: Go ahead, Mr. Reilly.

11 MR. REILLY: The evidence is in. We've sat  
12 here. We all know what the claims are. We've seen the  
13 claims.

14 If they want to put them in categories -- we are  
15 trying to do that to satisfy their issue to find a middle  
16 ground here and we're willing to put them into buckets that  
17 the jury can understand. And I think that's an appropriate  
18 way to handle that. I think other courts have done it.  
19 I've seen it done at the NAB, when they do false advertising  
20 claims, they patch them together. It's a reasonable  
21 approach and is what makes sense to the jury. To give them  
22 all of, it's going to be overwhelming.

23 THE COURT: I agree. If you want to submit  
24 something else, I have already told you, I'm not going to  
25 consider it, go ahead, Mr. Ryan. You be the bull in the



:06:09 1 china shop.

:06:10 2 MR. RYAN: I just want the clarification.

:06:11 3 THE COURT: You will see it when he submits it.

:06:11 4 MR. RYAN: May we have it first, Your Honor?

:06:12 5 THE COURT: I prefer that the two of you have it  
:06:13 6 first so that you can discuss it.

:06:15 7 MR. REILLY: Thank you, Your Honor.

:06:15 8 MR. RYAN: Thank you, Your Honor.

:06:16 9 MR. REILLY: We'll get that done, Your Honor.

:06:17 10 THE COURT: All right.

:06:18 11 MR. REILLY: I appreciate your patience and your  
:06:20 12 time.

:06:20 13 MR. RYAN: Thank you.

:06:29 14 (Court recessed at 6:06 p.m.)

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